#### **HUMAN CLONING PROHIBITION ACT OF 2003**

FEBRUARY 25, 2003.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. Sensenbrenner, from the Committee on the Judiciary, submitted the following

#### REPORT

together with

#### DISSENTING VIEWS

[To accompany H.R. 534]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill (H.R. 534) to amend title 18, United States Code, to prohibit human cloning, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

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#### PURPOSE AND SUMMARY

H.R. 534, the "Human Cloning Prohibition Act of 2003," amends title 18, United States Code, by establishing a comprehensive ban on human cloning and prohibiting the importation of a cloned em-

bryo, or any product derived from such embryo. Any person or entity that is convicted of violating this prohibition on human cloning is subject to a fine or imprisonment of not more than 10 years, or both. In addition, H.R. 534 provides a civil penalty of not less than \$1,000,000 for any person who receives a pecuniary gain from cloning humans. However, H.R. 534 does not prohibit the use of cloning technology to produce molecules, DNA, cells, tissues, organs, plants, or animals other than humans.

#### BACKGROUND AND NEED FOR THE LEGISLATION

Cloning, which literally means to make a copy, is the asexual reproduction of a precise genetic copy of a molecule, cell, tissue, plant, or animal. The word "cloning" can be used as a generic term to describe several different techniques of cloning. Molecular cloning refers to the copying of DNA fragments. For example, the human gene for insulin has been cloned into bacteria to produce insulin for the treatment of diabetes. In addition, human cells are

routinely cloned to study cancer or genetic diseases.

The cloning technique that could possibly allow for the production of individuals who are genetically identical to an already existing individual is known as "somatic cell nuclear transfer." This is the procedure that was used to clone Dolly the sheep in 1996, the first mammal ever to be cloned from an adult cell. Somatic cell nuclear transfer involves taking a mature but unfertilized egg, removing or deactivating its nucleus, and introducing a nucleus obtained from a specialized (somatic) cell of another adult organism. The egg is chemically treated so that it begins to behave as if fertilization has occurred. Once the egg begins to divide, the embryo is transferred to a female's uterus to initiate pregnancy. Since almost all the hereditary material of a cell is contained within its nucleus, the re-nucleated egg and the individual into which it develops are genetically identical to the organism that was the source of the transferred nucleus.

The announcement of the birth of Dolly brought into sharp focus the future possibility of cloning human beings along with all its inherent moral, ethical, and legal implications. The National Bioethics Advisory Commission (NBAC) was ordered to review the legal and ethical issues involved in the cloning of human beings and delivered its recommendations in June 1997. The NBAC agreed that the creation of a child by somatic cell nuclear transfer is scientifically and ethically objectionable because: 1) the efficiency of nuclear transfer is so low and the chance of abnormal offspring is so high that experimentation of this sort in humans was premature; and 2) the cloning of an already existing human being may have a negative impact on issues of personal and social well being such as family relationships, identity and individuality, religious beliefs, and expectations of sameness.

Currently, no clear regulations exist in the United States that would prevent a private group from attempting to clone a human being. The Food and Drug Administration (FDA) has announced that it has the authority to regulate human cloning, but that authority has been questioned by many experts and remains unclear

<sup>&</sup>lt;sup>1</sup>Cloning Human Beings, Report and Recommendations of the National Bioethics Advisory Commission (June, 1997).

today. According to the FDA, that authority comes in part from the Public Health Service (PHS) Act, which gives FDA the power to regulate "biological products" that are used to treat medical conditions. The FDA asserts that a human somatic cell clone (a cloned human embryo) is a "biological product" intended to treat a medical

condition, that condition being infertility.

The FDA also says it can regulate human cloning under the Food, Drug and Cosmetic Act (FD&C) because human somatic cell clones fall under the definition of "drugs." The FD&C Act defines drugs as "articles (other than food) intended to affect the structure or any function of the body." According to the FDA, a human somatic cell clone is an "article" that affects the structure and function of a woman's body by making her pregnant and would be subject to investigational new drug application requirements under the FD&C Act.

Although recent announcements by Clonaid that it had produced the first human clone seem to be nothing more than a hoax, there are reputable scientists and physicians that have announced their intention to attempt to produce the first human clone. Therefore, with no clear regulations in place, it has become imperative that Congress act to prevent this ethically and morally objectionable procedure.

Several other nations and international organizations have also enacted laws or issued policy statements prohibiting the cloning of human beings. Argentina, Australia, Belgium, Canada, Denmark, France, Germany, Israel, Japan, Norway, Peru, Slovakia, South Korea, Spain, Sweden, Switzerland, and the United Kingdom already have laws or have announced plans to pass laws prohibiting the cloning of human beings. In addition, the Denver Summit of Eight, the Council of Europe, the World Health Organization, UNESCO's International Bioethics Committee, the European Commission, and the Human Genome Organization have called for a worldwide ban on the cloning of human beings.

The possible production of a human clone raises a host of ethical questions. Cloning entails producing a person with a particular genetic code because of the attractiveness or usefulness of a person with that code. In this sense, by allowing human cloning, we are possibly legitimizing in principle the entire enterprise of designing

children to suit parental or social purposes.

It must also be recognized that any attempt at cloning a human being would be experimentation on the resulting child-to-be. Each experiment runs a high risk of failure. In all the animal experiments, fewer than two to 3 percent of all cloning attempts succeeded. Not only are there fetal deaths and stillborn infants, but many of the so-called "successes" are in fact failures. As has only recently become clear, there is a very high incidence of major disabilities and deformities in cloned animals that attain live birth. Attempts to clone human beings carry massive risks of producing unhealthy, abnormal, and malformed children.

It is well within Congress' power and prerogative to restrict or prohibit the means used by researchers that threaten interests in which the citizens of this country have a legitimate concern. As the National Bioethics Advisory Commission 1997 report pointed out, "(b)ecause science is both a public and social enterprise and its application can have a profound impact, society recognizes that the freedom of scientific inquiry is not an absolute right. . . ."

Some opponents of the bill would rather see a ban that would only prohibit cloning when there was an intent to initiate a pregnancy and would still allow scientists to clone human embryos for experimental purposes. This approach to prohibiting cloning would be much less effective and would inevitably be unenforceable. Once cloned embryos were produced and available in laboratories, it would be virtually impossible to control what was done with them. Stockpiles of cloned human embryos could be produced, bought and sold without anyone knowing it. Implantation of cloned embryos, a relatively easy procedure, would take place out of sight. At that point, governmental attempts to enforce a cloning ban would prove impossible to police or regulate. Creating cloned human children necessarily begins by producing cloned human embryos. The only effective way to prevent this is to prohibit all human cloning.

Opponents of a complete ban on human cloning also argue that H.R. 534 would have a negative impact in the field of stem cell research. Recent successes that scientists have had with adult stem cells does not support this argument. Adult stem cells are already being used successfully for therapeutic benefit in humans. This includes treatments associated with various types of cancer, to relieve systemic lupus, multiple sclerosis, rheumatoid arthritis, anemias, immunodeficiency diseases, and restoration of sight through regeneration of corneas. Furthermore, initial clinical trials have begun to repair heart damage using the patient's own adult stem cells. Adult stem cells are making good on what are only

promises of embryonic stem cells.

Few issues have ever created such a unified public opposition as the possibility of producing human beings who are genetically identical to an already existing individual. It took 277 stillborn, miscarried or dead sheep to make one Dolly the first cloned sheep. That failure rate, which has remained steady since 1997, is not acceptable for human beings. H.R. 534, by banning human cloning at any stage of development, provides the most effective protection from the dangers of abuse inherent in this rapidly developing field. By preventing the cloning of human embryos, there can be no possibility of cloning a human being.

#### **HEARINGS**

No hearings were held on H.R. 534 in the 108th Congress. H.R. 534 is identical to H.R. 2505 as reported by the Committee on the Judiciary in the 107th Congress. During the 107th, the Subcommittee on Crime held two hearings on June 7 and 19, 2001.<sup>2</sup> Testimony was heard from eight witnesses, representing eight organizations. The witnesses were: Dr. Leon R. Kass, Professor of Bioethics, The University of Chicago; Dr. David A. Prentice, Professor of Life Sciences, Indiana State University; Dr. Daniel Callahan, Director of International Programs for The Hastings Center; Robyn S. Shapiro, Esq., Professor of Bioethics, the Medical College of Wisconsin; Alex Capron, Esq., Professor of Law and Medicine, University of Southern California, School of Law; Dr. Jean Bethke

<sup>&</sup>lt;sup>2</sup>Human Cloning: Oversight Hearings Before the Subcomm. on Crime of the House Committee on the Judiciary, 107th Cong. No. 40 (2001).

Elshtain, Professor of Social and Political Ethics, The University of Chicago; Gerard Bradley, Esq., Professor of Law, Notre Dame Law School; Dr. Thomas Okarma, President and CEO of the Geron Corporation.

#### COMMITTEE CONSIDERATION

On February 12, 2003, the Committee met in open session and ordered favorably reported the bill H.R. 534 without amendment by a recorded vote of 19 yeas to 12 nays, a quorum being present.

#### VOTE OF THE COMMITTEE

1. An amendment was offered by Mr. Scott to insert language in the bill that would provide an exemption to the prohibitions of the bill for the importation of any product derived from an embryo if such product is unable to develop into a full human being. The amendment was defeated by rollcall vote of 12 yeas to 19 nays.

ROLLCALL NO. 1

	Ayes	Nays	Present
Ir. Hvde			
r. Coble		Χ	
r. Smith (Texas)		X	
r. Gallegly		X	
r. Goodlatte		٨	
r. Chabot		Х	
		x	
r. Jenkins			
r. Cannon		X	
r. Bachus		X	
r. Hostettler		X	
r. Green		Х	
lr. Keller		Х	
ls. Hart		Х	
r. Flake		Χ	
Ir. Pence		Χ	
Ir. Forbes		Χ	
Ir. King		Χ	
Ir. Carter		Χ	
Ir. Feeney		Χ	
ls. Blackburn		Χ	
Ir. Conyers	Χ	**	
Ir. Berman	Α.		
Ir. Boucher			
	Χ		
Ir. Nadler	X		
lr. Watt	X		
ls. Lofgren	Х		
ls. Jackson Lee			
ls. Waters	Х		
lr. Meehan	Х		
lr. Delahunt	Х		
r. Wexler	Χ		
s. Baldwin	Χ		
r. Weiner			
Ir. Schiff	Χ		
Ir. Sánchez	X		
lr. Sensenbrenner, Chairman	**	Χ	
Total	12	19	

<sup>2.</sup> An amendment was offered by Ms. Lofgren and Mr. Conyers to insert language in the bill that would provide an exception to

the prohibitions of the bill for the transfer of nuclei from somatic cells into unfertilized eggs to derive embryonic stem cells, including new cell lines, in order to further scientific understanding of embryonic stem cells, or to pursue treatments or products using embryonic stem cells, if the transfer is not used or intended to be used to initiate a pregnancy. The amendment was defeated by rollcall vote of 12 years to 19 nays.

ROLLCALL NO. 2

	Ayes	Nays	Present
Ar. Hyde			
Ar. Coble		Χ	
Mr. Smith (Texas)		X	
Mr. Gallegly		X	
Mr. Goodlatte		**	
Mr. Chabot		Χ	
Ar. Jenkins		X	
Mr. Cannon		X	
Mr. Bachus		X	
Ar. Hostettler		X	
		χ	
Ar. Green			
Ar. Keller		X	
As. Hart		X	
Mr. Flake		X	
Ar. Pence		X	
Mr. Forbes		Х	
Ar. King		Χ	
Mr. Carter		Χ	
Mr. Feeney		Χ	
As. Blackburn		Χ	
Mr. Conyers	Χ		
Mr. Berman			
Ar. Boucher			
Ar. Nadler	Χ		
Mr. Scott	X		
fr. Watt	X		
Ms. Lofgren	X		
As. Jackson Lee	٨		
	V		
As. Waters	X		
Ar. Meehan	X		
Mr. Delahunt	X		
Mr. Wexler	X		
As. Baldwin	Χ		
Mr. Weiner			
Mr. Schiff	Χ		
Mr. Sánchez	Χ		
Mr. Sensenbrenner, Chairman		Χ	
Total	12	19	

3. Final Passage. The motion to report favorably the bill, H.R. 534, was agreed to by a rollcall vote of 19 yeas to 12 nays.

ROLLCALL NO. 3

	Ayes	Nays	Present
Mr. Hyde			
Mr. Coble	Χ		
Mr. Smith (Texas)	Χ		
Mr. Gallegly	Χ		
Mr. Goodlatte			
Mr. Chabot	Χ		
Mr. Jenkins	Χ		

ROLLCALL NO. 3—Continued

	Ayes	Nays	Present
Mr. Cannon	Х		
Mr. Bachus	Χ		
Mr. Hostettler	X		
Mr. Green	X		
Vr. Keller	X		
Vs. Hart	X		
Vr. Flake	X		
Mr. Pence	X		
	X		
Ar. Forbes			
Ar. King	X		
Ar. Carter	Х		
Mr. Feeney	Х		
As. Blackburn	Х		
Mr. Conyers		Х	
Mr. Berman			
Mr. Boucher			
Mr. Nadler		Χ	
Mr. Scott		Χ	
Mr. Watt		Χ	
As. Lofgren		χ	
As. Jackson Lee		• •	
As. Waters		Х	
Ar. Meehan		X	
Mr. Delahunt		χ	
Ar. Wexler		X	
As. Baldwin		Х	
Ar. Weiner			
Ar. Schiff		Х	
Mr. Sánchez		Х	
Mr. Sensenbrenner, Chairman	Х		
Total	19	12	

#### COMMITTEE OVERSIGHT FINDINGS

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee reports that the findings and recommendations of the Committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

#### PERFORMANCE GOALS AND OBJECTIVES

 $H.R.\ 534$  does not authorize funding. Therefore, clause 3(c) of rule XIII of the Rules of the House of Representatives is inapplicable.

#### NEW BUDGET AUTHORITY AND TAX EXPENDITURES

Clause 3(c)(2) of House rule XIII is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

#### CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the Committee sets forth, with respect to the bill, H.R. 534, the following estimate and comparison prepared

by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act of 1974:

U.S. Congress, Congressional Budget Office, Washington, DC, February 25, 2003.

Hon. F. James Sensenbrenner, Jr., Chairman, Committee on the Judiciary, House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 534, the Human Cloning Prohibition Act of 2003.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Mark Grabowicz (for Federal costs), who can be reached at 226–2860, Greg Waring (for the State and local impact), who can be reached at 225–3220, and Paige Piper/Bach (for the private-sector impact), who can be reached at 226–2940.

Sincerely,

DOUGLAS HOLTZ-EAKIN.

Enclosure

cc: Honorable John Conyers, Jr. Ranking Member

H.R. 534—Human Cloning Prohibition Act of 2003.

H.R. 534 would prohibit any person or entity from performing or attempting to perform human cloning, participating in the human cloning process, or shipping or importing an embryo produced by human cloning. Anyone prosecuted and convicted under H.R. 534 would be subject to both criminal and civil fines and up to 10 years in prison.

Collections of criminal and civil penalties are recorded in the budget as governmental receipts (revenues), while criminal fines are deposited in the Crime Victims Fund and later spent. Thus, H.R. 534 could affect direct spending and receipts. CBO expects there is little likelihood that many cases would be prosecuted under the bill. Therefore, we estimate that enacting this legislation would have a negligible effect on receipts and direct spending.

H.R. 534 would impose both an intergovernmental mandate and a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA) because it would prohibit public and private entities from performing human cloning. The bill also would prohibit anyone from shipping or receiving a cloned embryo or any product derived from such an embryo. According to Government and industry sources, very little human cloning is currently being performed by public or private entities. CBO, therefore, estimates that the bill would impose minimal costs on State, local, or tribal governments, or the private sector over the next 5 years. Thus, the direct costs of the mandate would not exceed the thresholds established by UMRA (\$59 million for intergovernmental mandates and \$117 million for private-sector mandates in 2003, adjusted annually for inflation) in any of the first 5 years after the mandate would take effect.

The CBO staff contacts for this estimate are Mark Grabowicz (for Federal costs), who can be reached at 226–2860, Greg Waring (for the State and local impact), who can be reached at 225–3220, and Paige Piper/Bach (for the private-sector), who can be reached at 226-2940. This estimate was approved by Robert A. Sunshine, Assistant Director for Budget Analysis.

#### CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds the authority for this legislation in article I, section 8 of the Constitution.

#### SECTION-BY-SECTION ANALYSIS AND DISCUSSION

#### SECTION 1: SHORT TITLE

Section 1 of the bill states the short title of the bill as the "Human Cloning Prohibition Act of 2003."

#### SECTION 2: PROHIBITION ON HUMAN CLONING

Section 2 amends title 18, United States Code, by inserting after chapter 15, a new Chapter 16—Human Cloning. The new chapter 16 is comprised of two sections, numbered 301 and 302.

#### SECTION 301. DEFINITIONS.

This section defines the terms "human cloning", "asexual reproduction", and "somatic cell" as used in the bill.

#### SECTION 302. PROHIBITION ON HUMAN CLONING.

Section 302 establishes a prohibition on human cloning. Section 302(a) states that it shall be unlawful for any person or entity, public or private, in or affecting interstate commerce, knowingly, to perform or attempt to perform human cloning, to participate in an attempt to perform human cloning, or to ship or receive for any purpose an embryo produced by human cloning or any product derived from such embryo.

Section 302(b) provides that it shall be unlawful for any person or entity, public or private, knowingly to import for any purpose an embryo produced by human cloning, or any product derived from such embryo.

Section 302(c) states that any person or entity that is convicted of violating the prohibition on human cloning shall be fined or imprisoned not more than 10 years, or both. If such person or entity derived a pecuniary gain from the violation, then they would also be subject to a civil penalty of not less than \$1,000,000, and not more than an amount equal to the amount of the gross gain multiplied by 2, if that amount is greater than \$1,000,000.

Section 302(d) emphasizes that nothing shall restrict areas of scientific research not specifically prohibited by this bill, including research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans. This section also makes a clerical amendment to the table of chapters for part I of title 18, United States Code.

#### CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italics and existing law in which no change is proposed is shown in roman):

#### TITLE 18, UNITED STATES CODE

#### PART I—CRIMES

Chap. <b>1.</b>	General	provisions						Sec.
	*	*	*	*	*	*	*	
<i>16</i> .	Human (	Cloning						301
	*	*	*	*	*	*	*	

#### CHAPTER 16—HUMAN CLONING

Sec.

301. Definitions.

302. Prohibition on human cloning.

#### §301. Definitions

*In this chapter:* 

(1) HŪMAN CLONING.—The term "human cloning" means human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism (at any stage of development) that is genetically virtually identical to an existing or previously existing human organism.

(2) ASEXUAL REPRODUCTION.—The term "asexual reproduction" means reproduction not initiated by the union of oocyte

and sperm.

(3) Somatic cell.—The term "somatic cell" means a diploid cell (having a complete set of chromosomes) obtained or derived from a living or deceased human body at any stage of development.

#### §302. Prohibition on human cloning

(a) In General.—It shall be unlawful for any person or entity, public or private, in or affecting interstate commerce, knowingly—

(1) to perform or attempt to perform human cloning;

(2) to participate in an attempt to perform human cloning; or

(3) to ship or receive for any purpose an embryo produced by human cloning or any product derived from such embryo.
(b) IMPORTATION.—It shall be unlawful for any person or entity,

- (b) IMPORTATION.—It shall be unlawful for any person or entity, public or private, knowingly to import for any purpose an embryo produced by human cloning or any product derived from such embryo.
  - (c) PENALTIES.—

(1) CRIMINAL PENALTY.—Any person or entity that violates this section shall be fined under this title or imprisoned not

more than 10 years, or both.

(2) CIVIL PENALTY.—Any person or entity that violates any provision of this section shall be subject to, in the case of a violation that involves the derivation of a pecuniary gain, a civil penalty of not less than \$1,000,000 and not more than an amount equal to the amount of the gross gain multiplied by 2, if that amount is greater than \$1,000,000.

(d) Scientific Research.—Nothing in this section restricts areas of scientific research not specifically prohibited by this section, including research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans.

\* \* \* \* \* \* \* \*

#### MARKUP TRANSCRIPT

#### BUSINESS MEETING WEDNESDAY, FEBRUARY 12, 2003

HOUSE OF REPRESENTATIVES,

COMMITTEE ON THE JUDICIARY,

Washington, DC.

The Committee met, pursuant to notice, at 10:19 a.m., in Room 2141, Rayburn House Office Building, Hon. F. James Sensenbrenner, Jr., Chairman of the Committee, presiding.

\* \* \* \* \* \* \*

Now, pursuant to notice, I call up the bill H.R. 534, the "Human Cloning Prohibition Act of 2003" for purposes of markup and move its favorable recommendation to the House. Without objection, the bill will be considered as read and open for amendment at any point and all Members' statements may be submitted for the record.

[The bill, H.R. 534, follows:]

108TH CONGRESS 1ST SESSION

### H. R. 534

To amend title 18, United States Code, to prohibit human cloning.

#### IN THE HOUSE OF REPRESENTATIVES

February 5, 2003

Mr. Weldon of Florida (for himself, Mr. Stupak, Mr. Sensenbrenner, Mr. SMITH of Texas, Mr. Chabot, Mr. Lucas of Kentucky, Mr. Cannon, Mr. HALL, Mr. KELLER, Ms. HART, Mr. TAYLOR of Mississippi, Mr. DELAY, Mrs. MYRICK, Mr. BACHUS, Mr. BLUNT, Mr. FLETCHER, Mr. NORWOOD, Mr. PITTS, Mr. SHIMKUS, Mr. STEARNS, Mr. SMITH of New Jersey, Mr. VITTER, Mr. GOODE, Mr. WOLF, Mr. BRADY of Texas, Mr. HOEKSTRA, Mr. KILDEE, Mr. ADERHOLT, Mr. WICKER, Mr. COSTELLO, Mr. Sam Johnson of Texas, Mr. Lewis of Kentucky, Mr. Shuster, Mr. GOODLATTE, Mr. PICKERING, Mr. BURTON of Indiana, Mr. HUNTER, Mr. CANTOR, Mr. GUTKNECHT, Mr. HAYWORTH, Mr. MILLER of Florida, Mr. MCCRERY, Mr. RYUN of Kansas, Mrs. Jo Ann Davis of Virginia, Mr. WILSON of South Carolina, Mr. BOOZMAN, Mr. LINDER, Mr. MICA, Mr. SHADEGG, Mr. TERRY, Mr. COLLINS, Mrs. MUSGRAVE, Mr. KENNEDY of Minnesota, Mr. Pence, Mr. Rogers of Michigan, Mr. Tiberi, Mr. Ryan of Wisconsin, Mr. Forbes, Mr. King of Iowa, Mr. Everett, Mr. Akin, Mr. OSBORNE, Mr. TANCREDO, Mr. CAMP, Mr. DUNCAN, Mr. CRENSHAW, Mr. KING of New York, Mr. WAMP, Mr. FOSSELLA, Mr. COMBEST, Mr. HAYES, Mr. TIAHRT, Mr. BURNS, Mr. HOSTETTLER, Mrs. EMERSON, Mr. ISSA, Mr. CRANE, Mr. FEENEY, Mr. BUYER, Mr. FER-GUSON, Mr. GRAVES, Mr. DOOLITTLE, Mr. BARRETT of South Carolina, Mr. Green of Wisconsin, Mr. Sullivan, Mr. Rogers of Alabama, Mr. Brown of South Carolina, Mr. Kingston, Ms. Ros-Lehtinen, Mr. Pombo, Mr. Renzi, Mr. Hyde, Mr. Whitfield, Mr. Weller, Mr. PETRI, Mr. TOOMEY, Mr. BURGESS, Mr. DEMINT, Mr. HERGER, Mr. ORTIZ, Mr. REYES, Mr. MOLLOHAN, Mr. MANZULLO, Mr. NEY, and Mr. LAHOOD) introduced the following bill; which was referred to the Committee on the Judiciary

### A BILL

To amend title 18, United States Code, to prohibit human cloning.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Human Cloning Prohi-
- 5 bition Act of 2003".
- 6 SEC. 2. PROHIBITION ON HUMAN CLONING.
- 7 (a) IN GENERAL.—Title 18, United States Code, is
- 8 amended by inserting after chapter 15, the following:
- 9 **"CHAPTER 16—HUMAN CLONING**

#### 10 **"§ 301. Definitions**

- 11 "In this chapter:
- 12 "(1) Human cloning.—The term 'human
- 13 cloning' means human asexual reproduction, accom-
- 14 plished by introducing nuclear material from one or
- 15 more human somatic cells into a fertilized or
- 16 unfertilized oocyte whose nuclear material has been
- 17 removed or inactivated so as to produce a living or-
- ganism (at any stage of development) that is geneti-
- 19 cally virtually identical to an existing or previously
- existing human organism.

<sup>&</sup>quot;Sec.

<sup>&</sup>quot;301. Definitions.

<sup>&</sup>quot;302. Prohibition on human cloning.

	· · · · · · · · · · · · · · · · · · ·
1	"(2) ASEXUAL REPRODUCTION.—The term
2	'asexual reproduction' means reproduction not initi-
3	ated by the union of oocyte and sperm.
4	"(3) Somatic cell.—The term 'somatic cell'
5	means a diploid cell (having a complete set of chro-
6	mosomes) obtained or derived from a living or de-
7	ceased human body at any stage of development.
8	"§ 302. Prohibition on human cloning
9	"(a) In General.—It shall be unlawful for any per-
10	son or entity, public or private, in or affecting interstate
11	commerce, knowingly—
12	"(1) to perform or attempt to perform human
13	eloning;
14	"(2) to participate in an attempt to perform
15	human cloning; or
16	"(3) to ship or receive for any purpose an em-
17	bryo produced by human cloning or any product de-
18	rived from such embryo.
19	"(b) Importation.—It shall be unlawful for any per-
20	son or entity, public or private, knowingly to import for
21	any purpose an embryo produced by human cloning or any
22	product derived from such embryo.
23	"(c) PENALTIES —

1	"(1) CRIMINAL PENALTY.—Any person or enti
2	ty that violates this section shall be fined under this
3	title or imprisoned not more than 10 years, or both
4	"(2) Civil Penalty.—Any person or entity
5	that violates any provision of this section shall be
6	subject to, in the case of a violation that involves the
7	derivation of a pecuniary gain, a civil penalty of no
8	less than \$1,000,000 and not more than an amoun
9	equal to the amount of the gross gain multiplied by
0	2, if that amount is greater than \$1,000,000.
11	"(d) Scientific Research.—Nothing in this see
12	tion restricts areas of scientific research not specifically
13	prohibited by this section, including research in the use
4	of nuclear transfer or other cloning techniques to produce
15	molecules, DNA, cells other than human embryos, tissues
16	organs, plants, or animals other than humans.".
17	(b) CLERICAL AMENDMENT.—The table of chapters
18	for part I of title 18, United States Code, is amended by
19	inserting after the item relating to chapter 15 the fol
20	lowing:
	"16. Human Cloning 301"

#### [The prepared statement of Mr. Smith follows:]

PREPARED STATEMENT OF THE HONORABLE LAMAR SMITH, A REPRESENTATIVE IN Congress From the State of Texas

Mr. Chairman.

Ninety percent of those Americans polled last year said reproducing human beings is not acceptable. The American public recognizes that cloning raises serious moral, ethical, and scientific questions.

The method used to clone humans is very similar to the method used to clone animals. In order to successfully clone Dolly the sheep in 1997, experiments had produced 277 stillborn, miscarried, or dead sheep. In addition, research has shown that in the rare instance when a cloned embryo does survive these odds and is actually born, there is a significant risk of birth defects, disformities, and early deaths.

Scientists have not been able to show that these risks will be lowered in the near

future. We should not allow the manufacturing of unhealthy, disabled, or dead children as a byproduct of experimentation.

If we allow the practice of cloning, we are endorsing the practice of genetic engineering—human reproduction will become a manufacturing process through which children are custom made in science labs. And the living or deceased could be reproduced without their consent.

There are too many scientific uncertainties and too many risks involved to allow the cloning of humans. The only way to prevent it is to prohibit this dangerous prac-

Many other nations have taken steps to prohibit the cloning of humans. China, Argentina, Australia, Canada, South Korea, Spain, and the United Kingdom are just a few of the countries who already or are considering laws to ban human cloning.

Groups like the Council of Europe, the World Health Organization, the European Commission, and the Human Genome Organization have called for a worldwide ban

on the cloning of human beings.

President Bush opposes the practice of cloning and has stated that, "I believe all human cloning is wrong . . . anything other than a total ban on human cloning would be unethical. Allowing cloning would be taking a significant step toward a society in which human beings are grown for spare body parts, and children are engineered to custom specifications; and that's not acceptable."

The only way to ensure that a cloning ban is effective is to ban it entirely—H.R. 534 does just that. If we allow cloning for any reason, we will be unable to control what is done with cloned embryos. Anything other than a complete ban on cloning will be impossible to enforce.

This bill does not ban research in the use of cloning techniques to produce molecules, DNA, tissues, organs, plants, or cells other than human embryos. What it does is ensure that human beings will not be cloned.

We must not degrade the value of human life and we must not be reckless in our

pursuit of science and technology.

I urge my colleagues to support this bill.





#### Academy of Sciences urges ban on human cloning

(CNN) --The National Academy of Sciences recommended Friday that human reproductive cloning -- cloning to create a baby -- be legally banned.

"Human reproductive cloning should not now be practiced. It is dangerous and likely to fail," Dr. Irving Weissman, the chairman of the panel that made the recommendation, said while presenting the findings at a news conference.

Despite these misgivings, the panel said the issue of human reproductive cloning should be revisited in five years if a medical and scientific review suggests techniques may be safer, and if there is a public consensus that a review is warranted.

While the panel called for human cloning to be banned, it said that ban should not extend to the nuclear transfer technique, or cloning embryos for the purpose of extracting stem cells for the treatment of disease, "because of its considerable potential for developing new medical therapies for life-threatening diseases."

The group cited an earlier Academy of Sciences report that also supported this technique -- also called theuraputic cloning -- for stem cell research.

Dr. Bruce Alberts, president of the National Academy of Sciences, said the group decided to tackle the subject of human reproductive cloning to help inform public debate on the issue. He said the panel looked only at medical and scientific aspects of cloning, including protection of human subjects; it did not consider the ethical or moral implications of the research.

In a Friday news conference, Weissman explained that the panel had consulted experts in animal cloning, assisted reproductive technologies, medical and legal policy, and groups who want to clone a human, before coming to its conclusion.

It focused, he said, on the safety of the woman carrying the clone, the safety of the baby, and the risk to the egg donor. Data from animal studies show that there are serious risks to the mother, and that many cloned animals die or have severe abnormalities.

The rate of animal cloning successes, said panelist Dr. Mark Siegler, is "astonishingly low."

"There's no reason to believe that if carried out on human cells that (cloning) would be successful," he said.

Behavioral abnormalities are another concern, said panelist Dr. Maxine Singer. There is no animal data to determine whether clones might have behavioral problems, which would be of serious concern in any human cloning attempt.

http://cnn.health.printthis.clickability.com/pt/cpt?expire=-1&fb=Y&urlID=1895740&actior... 2/10/2003

CNN.com - Academy of Sciences urges ban on human cloning - January 18, 2002

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To be considered safe, the panel said, cloning techniques must be improved so that the rate of abnormalities in the fetus is no more than that seen with assisted reproductive technologies such as in-vitro fertilization.

In addition, tests would have to be developed to show that the embryos to be implanted are normal, and tests must be developed to monitor the fetus in utero for cloning-related defects.

Groups that say they are working to clone a human now lack the fundamental biological knowledge to do so, the panel said. They also have not demonstrated the safety of animal cloning nor developed appropriate testing methods to assure safety.

Find this article at: http://www.cnn.com/2002/HEALTH/01/18/academies.cloning/index.html

Check the box to include the list of links referenced in the article.

#### [The prepared statement of Mr. King follows:]

PREPARED STATEMENT OF THE HONORABLE STEVE KING, A REPRESENTATIVE IN Congress From the State of Iowa

Chairman Sensenbrenner, I strongly support the Human Cloning Prohibition Act of 2003, H.R. 534 for the following reasons.

I am unequivocally opposed to the cloning of human beings. The moral issues posed by human cloning, whether for reproduction or research, are profound and cannot be ignored.

I submit that we either halt cloning at the beginning, or we risk a disastrous impact on the true value of human life. Today, we must be clear in our definitions

and our intent, as ambiguity will surely lead to destructive ends.

Some opponents of this cloning ban argue that so-called "therapeutic cloning" should not be banned. In reality, the term "therapeutic cloning" is a dangerous misnomer. In fact, it can accurately be termed destructive cloning. Creating cloned human embryos for research purposes is anything but therapeutic for the cloned life who is abused and then killed during the experimentation process.

"Therapeutic" or destructive cloning creates a new human life for the express purpose of destroying him or her in order to do research. This practice violates the sanctity of human life. In my view, any scientific discoveries that might result from experimenting on cloned human embryos are ill-gotten gains that undermine the

fundamental right to life.

I am currently drafting a bill to protect cloned humans from the moment of inception in the event that cloning occurs illegally. I firmly believe that all human life is sacred and should be protected by the same laws, whether born or unborn.

In the debate on cloning in this country, cloning advocates have attempted to side-step the issue of personhood entirely. However, from the moment that human life comes into existence, either through sexual or asexual reproduction, developing humans are people of great worth and value. As such, all unborn children are entitled to the full protection under the law. I have been given no reason to abandon the belief that the unborn, including cloned embryos, are full-fledged members of our human community.

While I am strongly opposed to destructive cloning, I want to be clear that I do not oppose scientific developments that may cure diseases, as long as human life is protected. I believe a fundamental principle of scientific research involving humans is to do no harm. In fact, science has developed several ways of exploring cures for diseases through techniques that do not harm human embryos.

Chairman Sensenbrenner, I believe cloned human life should be protected at every stage of development from abuse and mistreatment at the hands of laboratory researchers. For this reason, I strongly support the House version of the cloning

ban, over the any other version, which would permit destructive cloning.

Mr. NADLER. Mr. Chairman?

Chairman Sensenbrenner. For what purpose does the gentleman seek recognition?

Mr. Nadler. I seek recognition to object.

Chairman Sensenbrenner. Objection is heard. The clerk

Mr. Nadler. The objection wasn't heard. You don't know what it is yet.

Chairman Sensenbrenner. I was

Mr. Nadler. Could I state it, sir?

Chairman Sensenbrenner. Without objection, the bill will be considered as read and open for amendment at any point. Is there

Mr. NADLER. I want to state an objection, yes.

Chairman Sensenbrenner. The objection is heard. The clerk will

Mr. NADLER. I'd like-Mr. Chairman, I think I'm entitled to state what the objection is.

Chairman Sensenbrenner. The gentleman has been around long enough to know to reserve the right to object-

Mr. Nadler. I reserve the right to object.

Chairman Sensenbrenner. Okay. The Chair will restate the UC request.

Without objection the bill will be considered as read and open for amendment at any point. Is there objection?

Mr. NADLER. I reserve the right to object.

Chairman Sensenbrenner. The gentleman from New York.

Mr. Nadler. Thank you. Mr. Chairman, the problem with this is that—forget the merits of the bill for the moment. We'll discuss that I assume in a few minutes. But this bill is being brought here without any consideration by the Subcommittee and without a public hearing. That's a violation of regular order. This is a new Congress, and we should, especially on a bill of this moment, observe regular order. There should have been a hearing, either at the Subcommittee or Committee levels. There should have been probably a markup at the Subcommittee. That you could dispense with, but at least a hearing.

Now, I understand that we are changing the rules of the House and of the Committee to roll votes and I would object to that, but we've already approved that. But to violate regular order on a bill of this moment, as the very first bill we're considering—I hope this isn't the precedent that we're going to—

Chairman SENSENBRENNER. Will the gentleman yield?

Mr. NADLER. In light of additional cases, I would hope that you might reconsider and schedule a hearing on this bill, and then we can have a proper markup.

Chairman SENSENBRENNER. Well, will the gentleman yield?

Mr. Nadler. Yes, I will.

Chairman Sensenbrenner. We didn't have Subcommittees in this Committee until a few moments ago when the rules were adopted, creating the Subcommittees and the Members were appointed on both sides of the aisle. The Chair certainly desired there to be public hearings on this bill or any other bill, but the issue is very bluntly this, and that is, is that the leadership intends to bring this bill out with or without Committee recommendation and Committee consideration the week after the Presidents' Day recess, and one of the reasons why I have scheduled a markup on this legislation is so that the Committee can put its oar in. There was kind of extenuating circumstances because the Chair intended to organize the Committee last Thursday, and that had to be canceled as a result of the memorial service for the astronauts that died in Columbia. So we got jammed and lost a week as a result of the tragedy that occurred and the commemoration that happened up at the cathedral.

So it is my hope that we will be able to have Committee consideration and hearings on practically all of the major bills that come before us, but because of the reasons just stated, we didn't have a hearing. I can say that if we can't report this bill out because of procedural objections, what will happen to this bill is the same thing that's happening to the Welfare Bill this week, and that is there will be no Committee consideration and it will be brought up on the floor.

The gentleman from New York.

Mr. NADLER. I thank the Chairman for his explanation and I apologize for forgetting to say "reserve the right to object" earlier today. It's been a long time since last year.

Let me just say that I appreciate the Chairman's explanation. And we certainly didn't have Subcommittees. We still could have held a hearing, but the really unfortunate thing about what the Chairman just explained to us, the determination of the leadership on this bill and the TANF bill, to bring up a bill with or without Committee consideration. I would hope that we will follow decent order. The rights of the minority, frankly, the rights of the American people to hear a discussion of all these different bills and of the various viewpoints, are frustrated if the leadership of the House, never mind the leadership of the Committee, but if the leadership of the House insists on bringing up bills without consideration by Committees, without markup, without hearings, and I would hope this would be the last time—I understand the extenuating circumstances, and I would hope that this will be the last time that that will happen if there aren't extenuating circumstances in the future, and with that, I'll withdraw my reservation.

Mr. Conyers. Reserving the right to object.

Chairman Sensenbrenner. The gentleman from Michigan.

Mr. Conyers. Thank you, Mr. Chairman. Mr. Chairman, you and I know that we may—we have in the past reached a point in time where we have to reflect our congressional responsibilities. Now, with all due respect for the leadership of the House of Representatives, there is no way that they can determine, for whatever reasons they may reach these determinations, when any duly constituted Committee shall or shall not have hearings. Hearings are an inherent right of the process of the House of Representatives. They are not arbitrary. They are not reached at the disposition of any one particular person in the House of Representatives. And it seems to me that we have reached a very important point in time at the beginning of the 108th Congress, where we decide who's running the House Judiciary Committee.

The Chairman and—

Chairman SENSENBRENNER. Will the gentleman yield?

Mr. Conyers. Yes, I will.

Chairman Sensenbrenner. No doubt about it, I am.

Mr. Conyers. Well, I'm happy to hear that because I was worried about the response, because if you are, and no doubt about it, then I, as the Ranking Member of this Committee, have to beseech you to listen to the requests of your colleagues who serve on this Committee under you. We need hearings on each and every bill, no exceptions, that comes before the Judiciary Committee, starting with this one. And so if you are in charge, this is—there's no more perfect time or place than for us to discuss what the person in charge does about the hearing on Human Cloning Prohibition Act of 2003.

I propose that we have hearings at the earliest convenience that the Chairman—at the Subcommittee level, and then that we have full Committee hearings, and then if it is the will of the majority of the Members on this Committee, we report the bill out as amended or we don't report it out. And that is a proposal that I have to put before you at this present moment.

Chairman SENSENBRENNER. Well, if the gentleman will yield.

Mr. Conyers. Of course.

Chairman Sensenbrenner. As I told the gentleman from New York, this is our chance of having Committee input on this legislation because if the leadership brings the bill to the floor as they have with the TANF bill, and as they did during the previous Chairman's tenure in office as Chairman of this Committee, then we lose whatever input we can have and the opportunity to file a Committee report which may or may not include dissenting or additional views, as the Members desire.

Given the timeframe that we have and what happened last week as a result of the tragedy involving the space shuttle, unfortunately, there wasn't time for a hearing, but I, you know, am very willing to protect the rights of the Members to the best I can, and

that's why we're having a markup today.

Is there objection to considering the bill as read and open—

Mr. Conyers. Yes, sir.

Chairman Sensenbrenner. Objection is heard and the clerk will

The CLERK. H.R. 534, To amend title 18, United States Code, to

prohibit human cloning.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Section 1. Short Title.

This Act may be cited as the "Human Cloning Prohibition Act of

Section 2. Prohibition on Human Cloning

(a) In General.—Title 18, United States Code, is amended by inserting after chapter 15, the following:

Chapter 16—Human Cloning. Section 301. Definitions

In this chapter:

(1) Human Cloning. The term "human cloning" means human asexual reproduction accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism (at any stage of development) that is genetically virtually identical to an existing or previously existing human organism.

(2) Asexual Reproduction. The term "asexual reproduction" means reproduction not initiated by the union of oocyte and sperm.

(3) Somatic Cell. The term "somatic cell" means a diploid cell (having a complete set of chromosomes) obtained or derived from a living or a deceased human body at any stage of development.

Section 302. Prohibition on human cloning.

(a) In General.—It shall be unlawful for any person or entity, public or private, in or affecting interstate commerce, knowingly

(1) to perform or attempt to perform human cloning;

(2) to participate in an attempt to perform human cloning; or (3) to ship or receive for any purpose an embryo produced by human cloning or any product derived from such embryo.

- (b) Importation.—It shall be unlawful for any person or entity, public or private, knowingly to import for any purpose an embryo produced by human cloning or any product derived from such embryo.
  - (c) Penalties.—

(1) Criminal penalty.—Any person or entity that violates this section shall be fined under this title or imprisoned not more than 10

years, or both.

(2) Civil penalty.—Any person or entity that violates any provision of this section shall be subject to, in the case of a violation that involves the derivation of a pecuniary gain, a civil penalty of not less than \$1,000,000 and not more than an amount equal to the amount of the gross gain multiplied by 2, if that amount is greater than \$1,000,000.

(d) Scientific Research.—Nothing in this section restricts areas of scientific research not specifically prohibited by this section, including research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans.

(b) Clerical Amendment.—The table of chapters for part I of title 18, United States Code, is amended by inserting after the item re-

lating to chapter 15 the following: 16. Human Cloning . . . . 301.

Chairman Sensenbrenner. The question is on reporting the bill favorably.

Mr. NADLER. Mr. Chairman?

Chairman Sensenbrenner. The gentleman from New York.

Mr. Nadler. Question on a point of information on the bill.

Chairman SENSENBRENNER. Which point?

Mr. Nadler. On page 3, lines 16 through 18, actually starting line 9. It says, "It shall be unlawful for any person," etc., "knowingly," line 16, "to ship or receive for any purpose an embryo produced by human cloning or any product derived from such embryo."

My question is, does that mean that if research were conducted

abroad, in England let's say-

Chairman ŠENSENBRENNER. Oh, the gentleman will strike the last word and is recognized for 5 minutes.

Mr. NADLER. No, I'm asking a question. This is not—

Chairman Sensenbrenner. Well, this is part of the debate, so. Mr. Nadler. No, it's not a debate. I want to ask a question. I will then strike the last word.

The question is simply, does it or does it not mean the following: that if research were conducted abroad and if what they call therapeutic cloning was done, and if let's say a vaccine for cancer were developed, that it would be a crime under this bill to import that vaccine—not embryos, but a product derived—to import that vaccine to give to cancer patients? Would that be a crime under this bill or would it not, under this section?

Chairman Sensenbrenner. Does the gentleman—who wishes to answer this? The gentleman from North Carolina move to strike the last word?

Mr. Coble. If the product—

Chairman Sensenbrenner. The gentleman is recognized for 5 minutes.

Mr. Coble. If the product was derived from a human cloned embryo, yes.

Mr. NADLER. Thank you. Now, Mr. Chairman, I'd like to strike the last word.

Chairman Sensenbrenner. The gentleman yield back his time? Mr. Coble. Yield back my time, Mr. Chairman.

Chairman Sensenbrenner. The gentleman from New York is

recognized for 5 minutes.

Mr. Nadler. Thank you, Mr. Chairman. This debate on this bill can be summarized very simply. This is a debate based on the majority's inclusion in this bill of a religious conviction, and that religious conviction, which is held by some denominations but not by others, is that at the moment of conception, or rather at the moment—at the moment of the formation of a cell with 46 chromosomes, whether by conception or by cloning techniques, a new human life is formed.

Now, I'm not going to debate that point. From a religious point of view some denominations think yes. Other denominations, such as apparently Senator Hatch said the Mormons, for instance, think no. We should not be criminalizing fields of research which could yield all kinds of benefits for humanity and for people, not to mention criminalizing the importation of vaccines or other cures for diseases that may be developed abroad because we adopt one religion or several religions, but one religious view of an unanswerable

question, which is when life begins.

If you read the Bible, for example, it says if you, if you attack a woman deliberately and the fetus dies, you should pay her compensation. Obviously it's not considered that the fetus at that point for all purposes was a human being because otherwise it would be murder. But I'm not saying that we should adopt the biblical view. I'm saying it's no business of ours to adopt any religious point of view and seek to impose it on everyone else, which is what this bill does. And we can debate from here to kingdom come when life begins, and people will say from a scientific point of view it begins when a cell has the potential to start dividing and create a new organism. Well, one can as easily argue that from a scientific point of view life never begins, because the DNA just keeps dividing and recombining, divides every few minutes and recombines once a generation, but it goes on and on and on. We have the DNA of our ancestors.

When one become an individual life people will differ on. This bill, by prohibiting reproductive cloning, which I think most Members would agree we probably ought to do, and therapeutic cloning, if that is the correct term, which simply means the creation of a 1-celled or a 5-celled organism which you then use for research or for curing diseases, which from my point of view is not a human being—and I understand this comes into the abortion debate. If it's a human being the moment it's one cell, then obviously you shouldn't have abortion because it's murder. If it isn't a human being right away, then maybe you should have abortion permitted. It's a whole different debate. We've been through that the last 40 years.

But this bill is really a fundamentalist bill. It goes as far as you can go and says the moment you have one cell capable of dividing and—capable of potential life, that that is a life, that it should be murder, and that we should criminalize all aspects of that.

Personally, I think that's wrong. I think that's a—it's a—people can choose as a matter of religion or conscience to believe that, but Congress ought not to impose that view on the many millions of people who as a religious view in this country do not believe that, and we should not limit the research and we should not condemn

to death—and if you're talking about a right to life, what do you say about a bill that to save single-celled organisms, single-celled organisms with no brain, no senses, no feeling, no anything, will condemn to death thousands of tens of thousands of people, of fully developed human beings for lack of the product, for lack of the vaccines, for lack of the drugs, for lack of the products that could be developed using this? This bill sentences to death tens of thousands, maybe millions of people over generations to an early death because of—because—and it does so in the name of imposing a particular religious view on the entire United States.

It's wrong morally. It's wrong in terms of imposing a religious view. People are entitled to their religious views. They're entitled to conduct themselves accordingly. But no one should impose that religious view on all of society. I urge the rejection of this bill as drafted unless it is amended to limit it to what is called reproduc-

tive cloning.

I yield back.

Chairman Sensenbrenner. The bill will now be considered for amendment by section. The clerk will read Section 1.

The CLERK. Section 1. Short Title.

This Act may be cited as the "Human Cloning Prohibition Act of 2003."

Chairman Sensenbrenner. Are there any amendments to Section 1?

Mr. Schiff. Mr. Chairman?

Chairman SENSENBRENNER. For what purpose does the gentleman from California, Mr. Schiff, seek recognition?

Mr. Schiff. Mr. Chairman, I have an amendment at the desk. Chairman Sensenbrenner. The clerk will read the amendment.

The CLERK. Amendment in the nature of a substitute to H.R. 534, offered by Mr. Schiff. Strike all after the enacting clause and insert the following.

Mr. COBLE. Mr. Chairman, reserve a point of order.

Chairman Sensenbrenner. Point of order is reserved. The clerk will continue to read.

The Clerk. Section 1, Short Title——

Mr. Schiff. Mr. Chairman, may the bill be considered as read? Chairman Sensenbrenner. Without objection, the amendment in the nature of a substitute is considered as read.

Does the gentleman from North Carolina wish to make a point of order?

Mr. COBLE. Mr. Chairman, I insist on my point of order in that it's not an amendment to Section 1.

Chairman Sensenbrenner. Does anybody else wish to be heard on the point of order?

Mr. Schiff. Mr. Chairman, if I may be heard on the point of order?

Chairman SENSENBRENNER. The gentleman from California is recognized on the point of order

recognized on the point of order.

Mr. Schiff. Mr. Chairman, the bill is in the nature—the amendment is in the nature of a substitute which would affect Section 1. It would affect all sections, but that would also include Section 1.

Chairman Sensenbrenner. Well, the Chair is prepared to rule. Only Section 1 is open to amendment since we are using the regular and unanimous consent was not granted, and since material

other than in Section 1 is proposed to be amended by this amendment, the point of order of the gentleman from North Carolina is sustained, and the amendment in the nature of a substitute is not in order.

Mr. Watt. Parliamentary inquiry, Mr. Chairman?

Chairman Sensenbrenner. The gentleman from North Carolina

will state his parliamentary inquiry.
Mr. Watt. Would the Chair inform us at what point Mr. Schiff's

amendment would be in order?

Chairman Sensenbrenner. If the gentleman would yield, the answer is amendments in the nature of a substitute, when there's no unanimous consent granted, takes place at the end of the reading of the clerk.

Are there amendments-

Mr. Watt. Would the Chairman—the Chairman is ruling that the amendment in the nature of a substitute is not going to be in order during this markup?

Chairman Sensenbrenner. No, that's not what the Chairman

said.

Mr. Watt. I'm sorry. I misunderstood, but-

Chairman Sensenbrenner. When unanimous consent is not granted and the bill has to be read, then amendments in the nature of a substitute are in order at the end of the reading of the clerk of the text of the bill that has been introduced.

Are there any amendments to Section 1?

[No response.]

Chairman Sensenbrenner. If there are no amendments to Section 1, the clerk will read Section 2.

The CLERK. Section 2. Purposes. It is the purpose of this Act to prohibit human cloning and to protect important areas of medical research including stem cell research.

Mr. Scott. Mr. Chairman?

Chairman Sensenbrenner. For what purpose does the gentleman from Virginia seek recognition?

Mr. Scott. I think my amendment No. 1, on page 4, line 16 is in this section.

Chairman Sensenbrenner. Because there is no unanimous consent to consider Section 2 read and open for amendment at any point, the gentleman from Virginia will have to offer his amendment at the proper time, and the clerk will continue to read.

Mr. Scott. Parliamentary inquiry, Mr. Chairman?

Chairman SENSENBRENNER. The gentleman will state his parliamentary inquiry.

Mr. Scott. Could the Chairman advise me when the proper time would be for this amendment on page 4, line 16?

Chairman Sensenbrenner. The Chair cannot because the Chair hasn't seen his amendment.

Mr. Scott. It's page 4, line 16.

Chairman SENSENBRENNER. Well, that may be a good time to propose your amendment then, on page 4, line 16, and the clerk will continue to read.

The CLERK. In this chapter:

(1) Human Cloning.—The term "human cloning" means human asexual reproduction accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism (at any stage of development) that is genetically virtually identical to an existing or previously existing human organism.

(2) Asexual Reproduction.—The term "asexual reproduction" means reproduction not initiated by the union of oocyte and sperm.

(3) Somatic Cell.—The term "somatic cell" means a diploid cell (having a complete set of chromosomes) obtained or derived from a living or a deceased human body at any stage of development.

Section 302. Prohibition on human cloning.

(a) In General.—It shall be unlawful for any person or entity, public or private, in or affecting interstate commerce, knowingly—

(1) to perform or attempt to perform human cloning;

(2) to participate in an attempt to perform human cloning; or

(3) to ship or receive for any purpose an embryo produced by

human cloning or any product derived from such embryo.

(b) Importation—It shall be unlawful for any person or entity, public or private, knowingly to import for any purpose an embryo produced by human cloning or any product derived from such embryo.

(c) Penalties.—

(1) Criminal penalty.—Any person or entity that violates this section shall be fined under this title or imprisoned not more than 10

years, or both.

- (2) Civil penalty.—Any person or entity that violates any provision of this section shall be subject to, in the case of a violation that involves the derivation of a pecuniary gain, a civil penalty of not less than \$1,000,000 and not more than an amount equal to the amount of the gross gain multiplied by 2, if that amount is greater than \$1,000,000.
  - (d) Scientific Research.—
    Ms. LOFGREN. Mr. Chairman.

The CLERK. Nothing in this—

Ms. Lofgren. Mr. Chairman, I have an amendment at line 10. Chairman Sensenbrenner. As the Chair stated in response to the gentleman from Virginia, amendments to Section 2 are not in order until the clerk finishes the reading of Section 2. Then they are in order. The clerk will continue to read.

The CLERK. Nothing in this section restricts areas of scientific research not specifically prohibited by this section, including research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans.

(b) Clerical Amendment.—The table of chapters for part I of title 18, United States Code, is amended by inserting after the item relating to chapter 15 the following:

16. Human Cloning . . . . 301.

Chairman Sensenbrenner. Are there amendments to Section 2?

Mr. Scott. Mr. Chairman?

Chairman SENSENBRENNER. For what purpose does the gentleman from Virginia seek recognition?

Mr. Scott. Mr. Chairman, I have an amendment to Section 2. Chairman Sensenbrenner. The clerk will read the amendment. Mr. Scott. Amendment No. 1.

Chairman Sensenbrenner. Scott 1.

The CLERK. Amendment to H.R. 534 offered by Mr. Scott, page 4, line 16——

Mr. Scott. Mr. Chairman, I ask unanimous consent that the amendment be considered as read.

Chairman SENSENBRENNER. Well, let's—since we're reading everything, we can read your amendment too.

The clerk will continue to read.

Mr. WATT. Is that an objection, Mr. Chairman?

Chairman SENSENBRENNER. That is an objection from the Chair. Mr. WATT. All right.

Chairman Sensenbrenner. The clerk will continue to read.

The CLERK. Strike the close quotation mark and the period that follows.

Page 4, after line 16 insert the following:

(e) Exemption of Medical Treatment—The prohibitions of this section do not apply to the shipping, receipt, or importation—

Chairman Sensenbrenner. I now ask unanimous consent that the amendment—

Mr. WATT. I object.

Chairman Sensenbrenner. Okay. The clerk will continue to read.

The CLERK.—for use in medical treatment of any product derived from an embryo (including pluripotent stem cells) if such product is unable to develop into a full human being.

[The amendment follows:]

# AMENDMENT TO H.R. 534 OFFERED BY M. Scott

- 1 Page 4, line 16, strike the close quotation mark and
- 2 the period that follows.
- 3 Page 4, after line 16, insert the following:
- 4 "(e) Exemption of Medical Treatment.—The
- 5 prohibitions of this section do not apply to the shipping,
- 6 receipt, or importation for use in medical treatment of any
- 7 product derived from an embryo (including pluripotent
- 8 stem cells) if such product is unable to develop into a full
- 9 human being."



Chairman Sensenbrenner. Gentleman from Virginia is recognized for 5 minutes.

Mr. Scott. Thank you, Mr. Chairman. Mr. Chairman, this—the bill would ban not only the importation of embryos produced under the broad definition of cloning, but also ban the importation of, "any product derived from such embryo." And that's even where it is impossible for the product to be developed into a full human being. What this means is, that if a life-saving medicine or therapeutic product is developed in one of the many countries outside the United States that allows nonreproductive research or therapeutic cloning, only those wealthy enough to travel there and pay

for the product can be saved.

That's both unnecessary to prevent human cloning and structurally unfair, because even though the bill might prohibit research involving nuclear transfer techniques, it would still be legal in Great Britain and elsewhere, were research is likely to produce significant medical advances. However, under the terms of this bill, Americans would be prohibited from importing stem cells or other medical treatments developed abroad simply because they were originally derived from a cloned embryo. That would not be beneficial medically. That would not prevent beneficial medically acceptable treatments that could save or improves lives for thousands of Americans with Parkinson's, Alzheimer's, diabetes, heart disease, cerebral palsy or a host of other conditions currently thought to be incurable.

If the medical science produced—if medical science produces a miracle cure for one of these diseases, the United States Government should not stand in the way or require its citizens to travel outside its borders for such life-saving techniques, and so this amendment would not require FDA oversight of medical treatment, nor promote the importation of treatments that are ineffective or unsafe. It would merely remove those aspects of the bill which would keep safe and effective medical treatments out of the hands of Americans who desperately need them.

I would hope that we would adopt this amendment, and I yield back the balance of my time.

Chairman Sensenbrenner. The gentleman from North Carolina, Mr. Coble.

Mr. Coble. Mr. Chairman, I oppose the amendment.

Chairman SENSENBRENNER. The gentleman is recognized for 5 minutes.

Mr. Coble. I won't take 5 minutes.

This amendment would provide an exemption to the prohibition to the bill for the importation of any product derived from an embryo if such product is unable to develop into a full human being.

Effectively, Mr. Chairman, I think this exemption would allow for the importation of stem cells derived from cloned embryos. By including this amendment in the bill, we would be creating a financial incentive for companies outside the United States to produce more cloned human embryos in order to make a greater profit from the sale of stem cells in the United States. With more cloned human embryos in the world, it would only be a matter of time, it appears to me, before they are illegally being used to create a cloned human baby. If we want to prevent cloned human children, we must seek to stop the process at the beginning. If this amend-

ment were agreed to, it would create an easy opportunity for a scientist or a company to avoid the prohibition on cloning.

I yield back, Mr. Chairman.

Chairman Sensenbrenner. The question is on the Scott Amendment. Those in favor will say aye.

Opposed, no.

The noes appear to have it.

Mr. Watt. Can we have a rollcall vote?

Chairman SENSENBRENNER. rollcall is demanded. Pursuant to the authority granted to the Chair by the Committee rules, the vote on the Scott amendment will be postponed, and will be taken at the end of offering of all of the amendments to this bill.

Are there further amendments? Mr. NADLER. Mr. Chairman?

Chairman Sensenbrenner. The gentleman from New York, Mr. Nadler.

The gentleman from Virginia have another amendment?

Mr. Scott. I have another amendment.

Chairman Sensenbrenner. The clerk will report the amendment.

The CLERK. Amendment to H.R. 534 offered by Mr. Scott of Virginia. Add at the end of the bill the following:

Section 3. Study by the General Accounting Office. Mr. Coble. Mr. Chairman, I reserve a point of order. Chairman Sensenbrenner. Point of order is reserved.

Mr. Scott. Mr. Chairman, could the amendment be considered as read?

Mr. Watt. Reserving the right to object.

Chairman Sensenbrenner. The clerk will continue to read the amendment.

The CLERK. (a) In General.—The General Accounting Office shall conduct a study to assess the need (if any) for amendment of the prohibition on human cloning as defined in Section 301 of title 18, United States Code, as added by this Act, which study should include—

Chairman Sensenbrenner. Without objection, the amendment is—

Mr. WATT. Reserving the right to object.

Chairman SENSENBRENNER. Without objection, the amendment is considered as read.

Mr. WATT. I object then. Mr. Chairman, I would like to reserve the right to object to——

Chairman SENSENBRENNER. Well, the clerk will continue to read then.

Mr. Watt. Reserving the right to object, may I be heard?

Chairman SENSENBRENNER. I withdraw my unanimous consent

request. The clerk will continue to read.

The CLERK. (1) a discussion of new developments in medical technology concerning human cloning and somatic cell nuclear transfer, the need (if any) for somatic cell nuclear transfer to produce medical advances, current public attitudes and prevailing ethical views concerning the use of somatic cell nuclear transfer, and potential legal implications of research in somatic cell nuclear transfer; and

(2) a review of any technological developments that may require that technical changes be made to Section 2 of this Act.

(b) Report.—The General Accounting Office shall transmit to the Congress, within 2 years after the date of enactment of this Act, a report containing the findings and conclusions of its study, together with recommendations for any legislation or administrative actions which it considers appropriate.

[The amendment follows:]

### AMENDMENT TO H.R. 534 OFFERED BY MR. SCOTT OF VIRGINIA

Add at the end of the bill the following:

1	SEC. 3.	STUDY	BY THE	GENERAL.	ACCOUNTIN	G OFFICE.
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2	(a) IN GENERAL.—The General Accounting Office
3	shall conduct a study to assess the need (if any) for
4	amendment of the prohibition on human cloning, as de-
5	fined in section 301 of title 18, United States Code, as
6	added by this Act, which study should include—

- (1) a discussion of new developments in medical technology concerning human cloning and somatic cell nuclear transfer, the need (if any) for somatic cell nuclear transfer to produce medical advances, current public attitudes and prevailing ethical views concerning the use of somatic cell nuclear transfer, and potential legal implications of research in somatic cell nuclear transfer; and
- 15 (2) a review of any technological developments 16 that may require that technical changes be made to 17 section 2 of this Act.
- 18 (b) Report.—The General Accounting Office shall 19 transmit to the Congress, within 2 years after the date 20 of enactment of this Act, a report containing the findings 21 and conclusions of its study, together with recommenda-



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- 1 tions for any legislation or administrative actions which
- 2 in considers appropriate.



Chairman Sensenbrenner. The gentleman from Virginia is recognized for 5 minutes, and I would ask him to yield.

Mr. Scott. I yield.

Chairman Sensenbrenner. The gentleman from Virginia offered a similar amendment when the Committee considered this legislation last year, and at the time of consideration, I stated that I thought that his amendment was a good idea, and I still believe this amendment is a good idea. However, the consequence of this Committee offering the amendment or adopting the amendment at this point in time will trigger a sequential referral to the Committee on Energy and Commerce.

I would make the same offer that I made to the gentleman from Virginia last year, in that I would support the right of the gentleman to offer his amendment on the floor when this bill comes up before the Rules Committee, so that we don't have the Committee on Energy and Commerce ending up having jurisdiction over Judiciary Committee matters, it he would withdraw the amend-

Mr. Scott. Under those circumstances, Mr. Chairman, I appreciate your cooperation, and ask unanimous consent to withdraw the amendment.

Chairman Sensenbrenner. Without objection, the amendment is withdrawn.

Are there further amendments to Section 2? The gentlewoman from California, Ms. Lofgren?

Ms. LOFGREN. Mr. Chairman, I have an amendment at the desk. Chairman SENSENBRENNER. The clerk will report the amend-

The CLERK. Amendment to H.R. 534, offered by Ms. Lofgren and Mr. Convers.

Page 4, after line 10, insert the following:

(d) Exceptions.—The prohibitions of this section do not apply to the transfer of nuclei from somatic cells into unfertilized eggs to derive embryonic stem cells-

Chairman Sensenbrenner. Without objection, the amendment is considered as

Mr. WATT. Objection.

Chairman Sensenbrenner. An objection is heard, and the clerk will continue to read.

The CLERK. —including new cell lines, in order to further scientific understanding of embryonic stem cells, or to pursue treatments or products using embryonic stem cells, if the transfer is not used or intended to be used to initiate a pregnancy. Page 4, line 1, strike "(d)" and insert "(e)."

[The amendment follows:]

## AMENDMENT TO H.R. 534 OFFERED BY Ms. LOFGREN AND MR. CONYERS

Page 4, after line 10 insert the following:

- 1 "(d) Exceptions.—The prohibitions of this section
- 2 do not apply to the transfer of nuclei from somatic cells
- 3 into unfertilized eggs to derive embryonic stem cells, in-
- 4 cluding new cell lines, in order to further scientific under-
- 5 standing of embryonic stem cells, or to pursue treatments
- 6 or products using embryonic stem cells, if the transfer is
- 7 not used or intended to be used to initiate a pregnancy.".

Page 4, line 11, strike "(d)" and insert "(e)".



Chairman SENSENBRENNER. The gentlewoman from California is recognized for 5 minutes.

Ms. LOFGREN. Thank you, Mr. Chairman.

I think if this bill were limited to a ban on reproductive cloning, this would be a very short markup because I believe that every Member of this Committee is opposed to cloning a child and would vote to prohibit it under law, but the bill before us goes much farther. It cuts the leg out of promising medical research, it prohibits therapeutic cloning, also known as somatic cell nuclear transfer.

Somatic cell nuclear transfer involves taking an unfertilized egg, removing or deactivating its nucleus and introducing a nucleus obtained from a special somatic cell, such as a skill cell. Scientists believe that these stem cells are less likely to be rejected after transplant, since they have the same genetic properties as the recipient. They could also help scientists learn how and why diseases occur.

Therapeutic cloning has nothing to do with cloning a human being. There is no fertilization of the egg by sperm, there's no implantation in the uterus, there is no pregnancy, there is no child. Therapeutic cloning has everything to do with saving lives and discovering cures to some of the most debilitating injuries and diseases, including Alzheimer's, Parkinson's, heart disease, diabetes, spinal cord injury, cerebral palsy, Huntington's disease, M.S., epilepsy, Tay-Sachs, mental retardation, sickle cell anemia and even kidney failure.

As has been mentioned by my colleague from New York, there are those who have religious beliefs that are at odds with therapeutic cloning. It seems to me that if you object on religious grounds to being cured of disease because you object to therapeutic cloning, fine, don't get your disease cured, but don't force millions of families affected by Alzheimer's or other diseases to sacrifice their hopes for your belief.

Should an embryonic stem cell, with no central service system and no chance of developing into a fetus, have the same rights as

a person suffering from diabetes? I don't think so.

I have heard from numerous people around the country in support of this amendment, including, and I ask that the letters be made a part of the record, Mr. Chairman—

Chairman Sensenbrenner. Without objection.

[The information referred to follows:]

T-967 P.02/05 F-187 1410 June 1 P.02/05 F-187 Washington, QC 20005 It 202-371-9746 ft 202-371-2760 www.idrf.org



dedicated to finding a cure

February 11, 2003

The Honorable Zoe Lofgren United States House of Representatives Washington, DC 20515

Dear Representative Lofgren:

On behalf of the Juvenile Diabetes Research Foundation International (JDRF), I write to express our strong support for your amendment to H.R. 534 that would permit the use of somatic cell nuclear transfer technology (SCNT) to produce embryonic stem cells. Without your amendment, H.R. 534—as presently written—would ban this important area of research.

As you know, most scientists believe that embryonic stem cell research holds tremendous potential to help find new treatments for, and identify ways to prevent, many diseases, including juvenile diabetes. More than 100 million Americans suffer from diseases that could benefit from this research.

JDRF strongly supports a ban on human reproductive cloning and your amendment would ensure that the bill continues such a ban. Thank you for your leadership on this important issue.

Sincerely,

Robert D. German

Chair, Government Relations Committee



Carolyn R. Aldigé President & Founder

February 11, 2003

The Honorable Zoe Lofgren 102 Cannon House Office Building Washington, DC 20515

Dear Congresswoman Lofgren:

I am writing in support of your amendment to H.R. 534, the "Human Cloning Prohibition Act of 2003," which will allow somatic cell nuclear transfer (SCNT) to be used to derive new stem cell lines and to pursue embryonic stem (ES) cell research.

The main purpose of somatic cell nuclear transfer is to further embryonic stem cell research. Embryonic stem cells have been recognized in scientific literature and by the National Institutes of Health as having important biological properties. Specifically, they are the only cells that can be turned into any type of cell in the body. Therefore, they could provide the scientific basis for research leading to cures and treatments for diseases and disabilities such as cancer, diabetes, Parkinson's disease, and spinal cord injury.

The Congress has consistently expressed its support for embryonic stem cell research. However, this bill would prevent scientists from cusuring that this research achieves its full potential. That is because it would prevent scientists from using SCNT, which could advance science to a point where millions of people will have access to lifesaving therapies developed using their own DNA and lead to the creation of new embryonic stem cells that will better enable researchers to investigate and understand the genetic causes of disease.

This amendment will not allow use of SCNT for reproductive cloning, but will allow scientists to use SCNT to further embryonic stem cell research. Forty Nobel Laureates, millions of patients, Nancy Reagan, and others have expressed support for SCNT to produce stem cells.

We thank you for your support.

Sincerely,

Carolyn Aldigè President and Founder



February 11, 2003

The Honorable Zoe Lofgren 102 Cannon House Office Building Washington, D.C. 20515

Dear Representative Lofgren:

On behalf of the Biotechnology Industry Organization (BIO), which represents more than 1,100 biotechnology companies, academic institutions and state biotechnology centers, I am writing to express BIO's support for your amendment to HR 534, the Human Cloning Prohibition Act of 2003.

BIO opposes human reproductive cloning – cloning to create a child. It is unsafe and unethical. However, alongside our nation's leading scientists, 40 Nobel Laureates, and former First Lady Nancy Reagan, we support therapeutic cloning (called somatic cell nuclear transfer or SCNT). This next step in embryonic stem cell research holds the potential to lead to cures and treatments for diseases and disabilities afflicting more than 100 million Americans, including diabetes, Alzheimer's and Parkinson's disease, autoimmune diseases and spinal cord injury. Unfortunately, HR 534, co-sponsored by Representatives Weldon, Stupak and others, would ban this promising research.

Embryonic stem cells, such as those that result from SCNT, have been recognized in the scientific literature and by the NIH as having important biological properties. Specifically, they are the only cells that can be turned into any type of cell in the body. SCNT will help ensure stem cell research reaches its full scientific potential by serving two important purposes:

a) First, with SCNT, science could advance to a point where millions of people will have access to lifesaving therapies developed using their own DNA. Many debilitating and deadly diseases and conditions are caused by damage to cells and tissue. Physicians and patients long for ample sources of rejection-proof transplantable replacement cells and tissue that could treat – and in many cases cure – such disorders. When combined with stem cell research, SCNT could prove the vital link in developing those treatments by helping scientists discover ways to make cells and tissues that are genetically identical to each patient's own cells.

1225 EVE STREET, N.W., SUPTE 401 WASHINGTON, D.C. 20005-5958 202-962-9200 PAX 202-962-9201 http://www.bio.org The Honorable Zee Lofgren February 11, 2003 Page Two

b) Second, SCNT could lead to the creation of new embryonic stem cells that will better enable researchers to investigate and understand genetic causes of disease. For example, scientists need to create new cells that actually harbor genetic diseases in order to study how these diseases affect the growth and development of other cells and tissues.

It is important to note that your amendment will not allow use of SCNT for reproductive cloning. It will not let the Raelians or anyone else clone a human being. It will simply allow medical researchers to continue their important work.

Thank you for your efforts on this important matter.

Michael I. Werner, Est. Michael II. Werner, Est. Vice President, Bioethics Biotechnology Industry Organization

MW:ks



February 11, 2003

The Honorable Zoe Lofgren United States House of Representatives Washington, DC 20515

#### Dear Representative Lofgren:

The Society for Women's Health Research strongly supports the amendment you have proposed to H.R. 534, which makes an exception to the ligislation so that the process of somatic cell nuclear transfer (SCNT) can be used to produce stem cells to aid in creating therapies for diseases.

The Society believes that reproductive cloning is both unsafe and unetlical. However, we agree with the Institute of Medicine (IOM) that any han on reproductive cloning must not interfere with important areas of research such as therapeutic cloning. We believe that the Lofgren amer dment strikes an appropriate balance between the need to prevent the reproductive cloning of a human being and the need to protect life-saving therapeutic research.

As you may be aware, women live longer but not necessarily healthier lives than men. Many of the illnesses for which therapeutic cloning research shows such promise have a particularly strong impact on women. For example, cardiovascular disease is the number one killer of American women. Other afflictions that might be cured or alleviated through this research, such as Alzheimer's disease and stroke, affect women in disproportionately high numbers.

We thank you for your leadership in introducing this important amendment to encourage medical breakthroughs to alleviate the suffering of comtless individuals—men, women, and children—struggling with life-threatening and debilitating diseases.

Sincerely,

Abuta Busel
Robe ta Biegel

Robe ta Biegel
Director of Government Relations



www.agingresearch.org

2021 K Street, NW | Suite 305 | Washington, DC 20006 τ 202.293.2856 | ε 202.785.8574

February 11, 2003

The Honorable Zoe Lofgren United States House of Representatives 102 Cannon House Office Building Washington, D.C. 20515

Dear Congresswoman Lofgren,

On Wednesday, February 12, 2003, the House Judiciary Committee will consider legislation, H.R. 534, sponsored by Congressman Dave Weldon (R-FL), which would ban human reproductive cioning. However, this bill would additionally ban Somatic Cell Nuclear Transfer (SCNT), also known as herapeutic cloning, to produce embryonic stem cells. The Alliance for Aging Research, an independent, not-for-profit organization, dedicated to improving the lives of older Americans through medical research, strongly supports your amendment to make an exception to the bill so that SCNT can be utilized to produce stem cells. Congress must ensure that legislation directly bans human reproductive cloning, yet avoids impairing SCNT technology, poised to cure millions of people suffering from deadly and debilitating diseases, such as Alzheimer's, Parkinson's, diabetes, and stroke.

The Alliance stands in strong opposition to cloning for human reproduction. Human reproductive cloning is unsafe, and broaches profound moral, religious and bioethical concerns. It is unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to create a human being using SCNT technology. However, H.R. 534, with its existing language, situates perilous limits on medical research and bans all forms cloning, including use of SCNT for treatment purposes. This bill criminalizes the very biomedical research that may provide the best hope to finding promising treatments and cures for dementia, arthritis, heart disease, cancer and other chronic health conditions of aging.

SCN1 involves removing the nucleus of an egg, replacing it with the material from the nucleus of a "somatic cell" (a skin, heart, nerve, or any non-germ cell), and stimulating this cell to begin dividing. Stem cells can be extracted 5-6 days later and used for this research, and the egg is never fertilized by sperm. The sole purpose of this technology is to develop treatments for disease. The Alliance fears that H.R. 534's ban on SCNT will have a devastating effect on the future of American biomedical research.

Millions of patients and their family members, Nancy Reagan, forty Nobel laureates, and others support embryonic stem cell research and aspire to see its potential maximized. It is a growing possibility that physicians one day, perhaps soon, will be able to replace damaged tissues using a person's own cells to treat blindness, coronary artery damage, spinal cord injuries and other serious disabilities that result from injuried, malfunctioning or aged cells. Our aging population may have the opportunity to benefit from this research and recent biomedical progress toward permanent cures against conditions that otherwise would compromise quality of life. The Alliance for Aging Research applauds and thanks you for your commitment and leadership in the fight to preserve the promise of medical research for all Americans.

National Chairmen John L. Steffens National Vice Chairman Robert N. Butter, MD Executive Director Duoled Parry

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William A. Heneticine, Ph.D. Numan Genome Sciences Inc. Desnie H. Longer, ND, JB Glassishikhline David W. Norton Johnson A Johnson Johnson A Johnson Phil. Reliament Research Foundation Mark Simon Robertson Steptens Settled

Science Advisory Bourd

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Carriel Perry Executive Director

Advancing Science. Enhancing Lives.

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### Coalition for the Advancement of Medical Research

February 11, 2003

The Honorable Zoe Lofgren United States House of Representatives 102 Cannon House Office Building Washington, DC 20515-0516

VIA FAX: 202-225-3336

Dear Representative Lofgren:

Within the next few weeks, you will be asked to vote on legislation to ban all forms of cloning, including research cloning that is vital to the development of new therapeutics that could assist millions of Americans. The Coalition for the Advancement of Medical Research (CAMR) – comprised of the nation's leading patient groups, universities and scientific societies – urges you to support a ban on reproductive cloning, but reject attempts to ban critically important research.

Representative David Weldon (R-FL) has reintroduced a bill, HR 534, that would not only ban reproductive cloning (which seeks to create humans) but would also prevent scientists from using a technique – somatic cell nuclear transfer (SCNT), sometimes called therapeutic cloning – that seeks to create stem cells compatible with a patient's immune system that could potentially cure disease. The overwhelming majority of the world's leading scientists believe SCNT has the potential to cure patients with their own DNA. To support HR 534 would be to deny hope to millions of Americans suffering from diabetes, heart disease, cancer, Parkinson's, Alzheimer's, spinal cord injuries and other life-threatening diseases and conditions.

A better alternative exists. Representative Jim Greenwood (R-PA) will introduce legislation that would prevent reproductive cloning but allow research using somatic cell nuclear transfer to continue.

We would like to thank you for not supporting a total ban on all cloning in the last Congress and hope that you will reject this approach again this year and instead vote to stop reproductive cloning while allowing research using SCNT to move forward. A vote for the Greenwood bill would do just that. SCNT could potentially be used to create stem cells that could be used to treat patients with degenerative diseases. More importantly, by developing stem cell lines from the cells of patients with particular diseases, scientists could study the mechanisms of genetic liness, provide laboratory tissue on which to test new drugs and develop treatments for these genetic disorders.

Again thank you for your vote last year to keep the promise of this research alive for millions of patients and families. We hope that you again choose to support those who are waiting for the treatments that our scientists hope to develop.

Sincerely yours,

Michael Manganiello

Michael Manganiello President CAMR Board of Directors

#### kirschfoundation

effecting change through strategic giving and advocacy

February 11, 2003

The Honorable Zoe Lofgren United States House of Representatives 227 Cannon House Office Building Washington, D.C. 20515

Dear Representative Lofgren:

On behalf of the Steven and Michele Kirsch Foundation, I am writing to add our strong support for your amendment to H.R. 534 (Weldon) that would create a permanent ban on human reproductive cloning while permitting research involving somatic cell nuclear transfer (SCNT).

Since 2001, the Kirsch Foundation has been actively working to protect federal funding for embryonic stem cell research as well as scientists' ability to conduct SCNT research. We are opposed to human reproductive cloning, and also believe that it poses a distraction to the enormous medical potential of SCNT. As an advocate for medical research, the Foundation is deeply concerned about restricting scientists' ability to use this potentially life-saving tool.

The Foundation agrees with the scientific community, and a majority of Americans, in believing that SCNT research should be allowed to continue given its potential for developing cures for life-threatening diseases and conditions including Alzheimer's disease, diabetes, Parkinson's disease, cancer, heart disease, and spinal cord injury. In light of such medical promise, a permanent moratorium on the practice of human reproductive cloning – while protecting SCNT research – is clearly in the nation's best interest.

The Kirsch Foundation applauds your leadership in sponsoring an amendment that ensures cures for devastating diseases continue to be developed.

Sincerely,

Susan E. Frank

Vice President, Public Policy

Board of Director Steven T. Kirsol Perry Olso Harry J. Sea

Officers
Kathleen Gwynn
Peter deCourcy Hero



University of Missourt-St. Louis Mo Dept. of Economic Development St. Louis Development Corp.

Marcia B. Mellitz President & CEO William B. Simon Vice President & COO Barbara Enneking Vice President for Development

February 12, 2003

Honorable Zoe Lofgren U. S. Representative Cannon House Office Building Washington, DC 20515

Dear Congresswoman Lofgren:

I am writing to support your amendment to the cloning bill that allows for the use of embryonic stem cells for therapeutic purposes. I am writing as a mother of an adult son who has been disabled since birth as a result of spinabifida, which causes paralysis that is similar to a spinal cord injury. I am also writing as President of the Center for Emerging Technologies in St. Louis, which is an incubator for medical technology companies.

It would be my hope that no other parent or child would have to endure the lifetime of physical and emotional pain that has been the result of my son's birth defect. I envision medical science evolving to a point where a child with such a birth defect could receive a stem cell transplant and be able to regenerate nerve cells in the spine at such an early age that there might be little or no residual effects.

The companies in our Center are developing cutting-edge medical technologies that have the potential to make a major impact on real people's lives. I hope that sometime soon we could have a company developing major breakthrough therapies using stem cells.

I commend you for your leadership in sponsoring this legislation. There could not be a great endorsement of support for life and the quality of life for all individuals.

Marcia Mellitz

4041 Forest Park Avenue • St. Louis, MO 63108 • Phone; (314) 615-6900 • Fax: (314) 615-6901 • B-mail: info@emerginglesch.org • http://www.omerginglesch.org

A Joint Endeavor of the Missouri Department of Franconic Development and the University of Missouri-St. Louis

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SANTA BARBARA . SANTA CRUZ

OFFICE OF THE PRESIDENT

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Senior Vice President-University Affairs

Office of Federal Governmental Relatio 1608 Rhode Island Avenue, NW Washington, D.C. 20036 Office (202) 974-6302 Fax (202) 974-6330 A. SCOTT SUDDUTH Acriston Vice Participat

February 12, 2003

Representative Zoe Lofgren U.S. House of Representatives 102 Cannon House Office Building Washington, DC 20515

#### Dear Representative Lofgren:

As the House Judiciary Committee prepares to markup HR 534, The Human Cloning Prohibition Act of 2003, I want to explain the University of California's position on this difficult moral and ethical issue. UC strongly opposes human reproductive cloning and supports legislation which would ban such cloning. The University, however, opposes HR 534 in its current form because this bill would reach beyond barning human reproductive cloning and would prevent scientists from using a technique known as somatic cell nuclear transfer (SCNT), sometimes called therapeutic cloning or research cloning. One important application of the SCNT technique is to create new embryonic stem cells, offering much opportunity for preventing and alleviating human disease, disability, and premature death.

The University of California strongly supports your effort to offer an amendment to HR 534 during markup which would create an exception to the ban proposed in the bill for purposes of deriving new embryonic stem cells. We appreciate your leadership on this issue and applaud your efforts to promote responsible and potentially therapeutic nuclear transplantation research.

Again, thank you for your leadership on this issue. If you have any questions please contact me at (202) 974-6302.

Sincerely,

A. Scott Sudduth

Ms. LOFGREN. The Juvenile Diabetes Research Foundation, the Cancer Research and Prevention Foundation, the Biotechnology Industry Organization, the Society for Women's Health Research, the Alliance for Aging Research, the Coalition for the Advancement of Medical Research, the Kirsch Foundation, and individuals who are suffering severe illness who hope that, through the advancement of science, they may one day find a cure.

I would note that being in support of therapeutic cloning and medical research is not out there. It's not some far-out thing to do. Recently, as has been reported in the paper, former First Lady Nancy Reagan wrote to Senator Orrin Hatch expressing her support for therapeutic stem cell research, and I'll quote just part of the letter that former First Lady Nancy Reagan wrote to Senator

Hatch. She says:

"I'm writing to offer my support for stem cell research and to tell you I'm in favor of new legislation to allow the ethical use of therapeutic cloning. Like you, I support a complete ban on reproductive cloning. However, I believe that embryonic stem cell research, under appropriate guidelines, may provide our scientists with many answers that are now beyond our grasp."

"Orrin, there are so many diseases that can be cured or at least helped that we can't turn our back on this. We've lost so much time

already. I can't bear to lose any more."

As this Committee knows, former President Ronald Reagan is himself suffering severely from the march of Alzheimer's, and just yesterday we passed, I believe without a single no vote, a celebration of President Reagan's birthday, his 92nd birthday. I would hope that, while celebrating the former President's birthday, we might also think about what steps we could take so that he and others suffering from diseases like his might have the hope of a cure.

We do know that the current state of events is insufficient for scientific research. This bill before us, without the amendment I have offered, would take the bold step of banning all Federal, as well as privately funded research, on embryonic stem cells, and it would also criminalize the importation of cures developed from therapeutic cloning.

The amendment before us would not permit reproductive cloning. It would not let the Raelian's or anyone else clone a human being.

It would simply protect important medical research.

Chairman Sensenbrenner. The gentlewoman's time has expired.

For what purpose does the gentleman from North Carolina seek recognition?

Mr. Coble. Mr. Chairman, I speak in opposition to the amendment

Chairman Sensenbrenner. The gentleman is recognized for 5 minutes.

Mr. COBLE. Mr. Chairman and Members, this amendment would make substantial and fundamental changes to the enforcement provisions of the underlying bill. Specifically, the prohibition of human cloning would be changed from banning all human cloning to only prohibiting human cloning with the intent to initiate a pregnancy. This approach is unenforceable, it seems to me. Once cloned embryos are produced and available in laboratories, I think it would

be virtually impossible to control what is done with them at this point.

In its testimony last year, the Department of Justice spokesman said that enforcing such a limited ban would put law enforcement in the unenviable position of having to impose new and unprecedented scrutiny over physicians in fertility clinics and/or research facilities to ensure that only fertilized embryos were being trans-

ferred to would-be mothers and not cloned embryos.

Dr. Leon Cass testified at a hearing in the 107th Congress that stockpiles of cloned human embryos could be produced, bought and sold without restrictions. Implantation of cloned embryos, a relatively simple procedure, I'm told, would inevitably take place. Attempts to enforce a cloning ban would improve near to impossible to monitor. Creating human—strike that. Creating cloned human children necessarily begins by producing cloned human embryos. If we want to prevent cloned children, we need to prevent cloned em-

It has been argued that H.R. 534 would have a negative impact on scientific research. This argument is unsupported both by the language bill and the testimony received by the Crime Subcommittee during the last Congress. The language of the bill specifically states that nothing shall restrict areas of scientific research not specifically prohibited by this bill, including research in the use of nuclear transfer or other cloning techniques used to produce molecules, DNA, cells, other than human embryos, tissues,

organs, plants, or animals other than humans.

Any cloning experience runs the risk of high failure. In all of the animal experiments, fewer than 2 to 3 percent of all cloning attempts succeeded. There were numerous fetal deaths and stillborn

deaths—stillborn births.

Based on these experiments, cloning human beings also carries massive risks of producing unhealthy, abnormal and malformed children. The only way to prevent this from happening is to adopt

the restrictions on human cloning, as set forth in H.R. 534.

As Professor Bradley, I think from Notre Dame, I believe, testified, the only effective way to prohibit human reproductive cloning is to prohibit all human cloning. Furthermore, the National Institutes of Health and the National Bioethics Advisory Commission have expressed serious concerns over creating embryos specifically for research purposes.

Mr. Chairman, I urge my colleagues to oppose the amendment

and support the provisions of the underlying bill.

Chairman SENSENBRENNER. The question is on the-

Mr. NADLER. Mr. Chairman?

Chairman Sensenbrenner. For what purpose does the gentleman from New York seek recognition?

Mr. NADLER. To strike the last word on this.

Chairman Sensenbrenner. The gentleman is recognized for 5

Mr. Nadler. Thank you, Mr. Chairman.

This amendment, as Mr. Coble said, goes to the heart of the bill and really simply says that we should not utilize this bill to prohibit development of embryonic stem cells from cloned embryos, if you will, for scientific research. Mr. Coble incorrectly states that this bill will not prevent scientific research, and he reads from the

bill when he says it shall not prevent scientific research except for what is specifically prohibited, which is almost all scientific research is specifically prohibited.

All scientific research with embryonic stem cells or any other products derived from a clone cell is specifically prohibited, which is a very large area of research, indeed, and that's not debatable. That's a fact.

This bill seeks to prevent a large area of research, and the question is should we do so.

Now, I want to address that because we keep saying that it is said that—let me address one other thing. Mr. Cass, whom the President and some others think is an eminent bioethicist and others think is a quack, has said that if you allow so-called therapeutic cloning, how can you prevent—it becomes almost impossible

to prevent reproductive cloning.

Well, that, frankly, is absurd. Because the fact is you're going to, whether you prevent therapeutic cloning or not, whether you prohibit therapeutic cloning or not, you're going to have to, if you want to prohibit so-called reproductive cloning, you're going to have to watch what's going on, but you don't have to watch what's going on in every petri dish. It would be a crime to implant an embryo in a human, in a woman's uterus. That's a crime. That you could see, and that's a very clear act, and either you do it or you don't do it. And if you make it criminal, as I think most of us agree it should be, it's a very clear thing to look at. You don't have to examine what's in the petri dishes.

So the slippery slope argument doesn't really apply. The real argument that applies, as I said, again, and I think people should be honest enough to admit that the real impetus for the ban in this bill on therapeutic cloning, so-called, is the feeling that a one-celled organism, a zygote, is a human being. That's what the right-to-life movement says, that's what some of the anti-abortion people say. They're entitled to their view, but that's—and if you agree with that, then this bill makes sense. If you don't agree with that, this

bill doesn't make sense.

I want to read from an article in the March 14, I think it's in *The Washington Post*, March 14 of last year. "The Nation's largest orthodox Jewish organizations declared their support yesterday for allowing scientists to clone human embryos for medical research, breaking with some conservative Christian groups on a topic of hot debate in the Senate."

"Nathan Diament, the Orthodox Union's director of Public Policy said that 'he hopes the State will help people to understand that there is a religiously informed moral basis for supporting this research that is at least as strong as the religiously informed moral

basis for opposing it."

"Edward Reichman, an orthodox rabbi and physician at Einstein College of Medicine in New York said the Jewish position is that a 'fertilized embryo in a petri dish does not have the same status of human life,' and if such an embryo can be used to cure diseases and save lives, 'that is something we would welcome with open arms."

"Muslim groups, Mormons and some mainline Protestant denominations, including the United Church of Christ and the Presbyterian Church, have supported such stem cell research."

"Opponents of the procedure argued that it involves the destruction of life, and in the words of Cardinal Theodore McCarrick of Washington, beckons scientists to 'take on the role of God and reduce humans to mere spare parts."

"Adin Steinsaltz, an Israeli rabbi and renowned Talmudic scholar, said Jews generally reject the notion that human beings should not 'interfere with the handiwork of God.' We believe that mankind is given not only the permission, but the admonition to make the world better," he said.

Now, my point from quoting this is not to say that any of these people I just quoted are right or wrong, but these are all different religious views, they're legitimate religious views, and it is wrong, it is wrong morally, it is wrong politically, it is wrong ethically to use political power in this Congress, in this Committee, to codify a particular religious view and to criminalize people with different religious views and to criminalize the conduct of people with different religious views, conduct that may save thousands and tens of thousands of human lives.

That's what this bill does. This amendment would correct that. Hopefully, this and several other amendments would correct that, but without this amendment or similar amendments, this bill adopts a particular religious view, says, in effect, to many people in this country, maybe the majority, we think your religious view is wrong and unethical or immoral or wrong, and we're going to use political power to impose a particular religious view so that we cannot cure you or your mother or your father of many different diseases and that you should have an early death.

This, frankly, is not only a wrong bill, but for that reason it's an immoral bill, and I support the amendment.

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The Washington Post

March 13, 2002, Wednesday, Final Edition

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**HEADLINE: 2 Jewish Groups Back Therapeutic Cloning;** Orthodox Leaders Break With Right

BYLINE: Alan Cooperman, Washington Post Staff Writer

BODY:

The nation's largest Orthodox Jewish organizations declared their support yesterday for allowing scientists to clone human embryos for medical research, breaking with conservative Christian groups on a topic of hot debate in the Senate.

The House passed legislation last year that would ban all human cloning, and the Senate may vote in April on an identical bill introduced by Sen. Sam Brownback (R-Kan.) and backed by the Bush administration. The Catholic Church, the Southern Baptist Convention and many Christian political action groups -- including Focus on the Family, the Family Research Council and the Christian Coalition -- also support a ban.

However, Sens. Dianne Feinstein (D-Calif.) and Arlen Specter (R-Pa.) have introduced bills that would allow the cloning of embryos for stem cell research while prohibiting attempts to implant a cloned embryo in a woman's womb to produce a cloned baby. That is the approach endorsed yesterday by the Union of Orthodox Jewish Congregations of America, which represents nearly 1,000 synagogues, and the Rabbinical Council of America, which consists of more than 1,000 Orthodox rabbis. "We must be careful to distinguish between cloning for therapeutic purposes -- which ought to be pursued, and cloning for reproductive purposes -- which ought to be pursued, and cloning for reproductive purposes -- which ought as a joint statement.

Nathan Diament, the Orthodox Union's director of public policy, said that he hopes the statement "will help people to understand that there is a religiously informed, moral basis for supporting this research that is at least as strong as the religiously informed, moral basis for opposing it."

Edward Reichman, an Orthodox rabbi and physician at New York's Einstein College of Medicine, said the Jewish position is that a "fertilized embryo in a petri dish does not have the status of human life," and if such an embryo can be used to cure diseases and save lives, "that is something we would welcome with open arms."

Reichman added that Jewish law might also allow the cloning of a baby, but "it is not something we would recommend" for a variety of reasons, including the high chance of deformities and the question of parentage.

"If a woman clones herself, who is the legal father?" he asked. "We would be creating people of ambiguous lineage."

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The dominant branches of American Judaism, the Reform and Conservative movements, have not yet adopted positions on cloning but appear likely to follow the Orthodox stand. A panel of Conservative rabbis may vote as early as today on a draft policy supporting "therapeutic cloning," according to its author, Rabbi Elliot N. Dorff.

The Reform movement is on record in favor of fetal tissue and stem cell research, and "the mood of the movement is to support therapeutic cloning as well," said Rabbi Richard Address, director of the Department of Jewish Family Concerns in the Union of American Hebrew Congregations.

The cloning debate is closely related to research on stem cells -- primitive cells that scientists say could treat a host of diseases. Last year, President Bush decided to support federal funding of stem cell research, but only if the cells are grown from existing lines, not from newly created embryos. Therapeutic cloning involves growing embryos in laboratories and destroying them after a few days, when stem cells are removed.

Muslim groups, Mormons and some mainline Protestant denominations, including the United Chuch of Christ and the Presbyterian Church (USA), have supported stem cell research. But Orthodox Jews are among the first religious groups to endorse therapeutic cloning.

Opponents of the procedure argue that it involves the destruction of life and, in the words of Cardinal Theodore McCarrick of Washington, beckons scientists to "take on the role of God and reduce humans to mere spare parts." Adin Steinsaltz, an Israeli rabbi and renowned Talmudic scholar, said Jews generally reject the notion that human beings should not "interfere with the handiwork of God."

"We believe that mankind is given not only the permission but the admonition to make the world better," he said.

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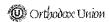
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## CLONING RESEARCH, JEWISH TRADITION & PUBLIC POLICY; A JOINT STATEMENT by the UNION of ORTHODOX JEWISH CONGREGATIONS of AMERICA and the RABBINICAL COUNCIL of AMERICA

Society today stands on the threshold of a new era in biomedical research. The wisdom granted to humans by our Creator has led to our greater understanding and knowledge of the building blocks of human life itself. Scientists revealed the existence and role of DNA and cellular science many years ago. Currently, scientists are not only able to describe the nature of cellular life, but manipulate it as well. We are now faced with the possibility of mastering the art of this manipulation to the point of being able to clone in research laboratories the cells that, in other circumstances, lead to fully developed human beings.

A debate has emerged in American society at large and among our elected leaders as to whether public policy should permit, encourage, restrict or ban the further conduct of this biomedical research. The issue is one with complex moral dimensions. On the one hand scientific research indicates that there is great life-saving potential in the results that can come from cloning research.\* On the other hand, we must be vigilant against any erosion of the value that society accords to human life

Our Torah tradition places great value upon human life; we are taught in the opening chapters of Genesis that each human was created in God's image. After creating man and woman, God empowered them to enter a partnership with Him in the stewardship of the world. The Torah commands us to treat and cure the ill and to defeat disease wherever possible; to do this is to be the Creator's partner in safeguarding the created. The traditional Jewish perspective thus emphasizes that maximizing the potential to save and heal human lives is an integral part of valuing human life. Moreover, our tradition states that an embryo in witro does not enjoy the full status of human-hood and its attendant protections. Thus, if cloning technology research advances our ability to heal humans with greater success, it ought to be pursued since it does not require or encourage the destruction of life in the process.

However, cloning research must not be pursued indiscriminately. We must be careful to distinguish between cloning for therapeutic purposes – which ought to be pursued, and cloning for reproductive purposes – which we oppose. Thus, this research must be conducted under strict guidelines and with strict limitations to ensure that the research is indeed

http://www.ou.org/public/publib/cloninglet.htm

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serving therapeutic purposes.

Consistent with this policy, we advocate that a fully funded and empowered oversight body comprised of scientists and ethicists be created to monitor this research. Relevant Executive-branch agencies and congressional committees should conduct periodic reviews as well. The oversight process should pay special attention to ensuring that the embryos used in this research are not brought to a point which constitutes human-hood.

We believe that the policy stated herein articulates the perspective of the Torah tradition and the community we represent and achieves the correct balance between pursuing new methods for saving human lives and maintaining the fundamental respect and sanctity of human life.

\* This joint statement specifically addresses our view on the subject of cloning technology research. We have previously set forth our views on the related subject of stem cell research in a document which may be found at <a href="http://www.ou.org/public/Publib/cloning.htm">http://www.ou.org/public/Publib/cloning.htm</a>

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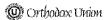
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JUNE 7, 2002

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#### Cloning, Between Panacea and Pandora's Box

#### By EDWARD REICHMAN

In the coming weeks Congress will try to reach a decision on one of the most explosive questions in bioethics and biotechnology: whether to permit the manufacture of human cells — or cloning — for the purpose of stem-cell research.

Advocates on both sides of the issue have tried to present it as a replay of the ongoing debate over abortion, since cloning and stem-cell research involve the deliberate production and destruction of human reproductive issue. This time, however, the camps have not broken down along traditional lines. Some traditional advocates of the pro-life view, including major representative bodies of Orthodox Judaism as well as some traditionalist Protestant groups, have taken what appears in some eyes to be a surprising and contrarian stance in favor of these new technologies.

To students of Jewish bioethics, the Orthodox position is neither surprising nor contrarian. It is merely an appropriate reading of the traditional sources in light of rapidly changing developments. This is the way of Jewish ethics: History changes, though our sources do not.

Some centuries ago, Galileo advanced the heliocentric theory, forcing us to redraw the astronomical map. This reconfiguration challenged Jewish theology, but the rabbis of that time rose to the challenge, accepted the truth and confronted the issues. Some centuries later, Darwin devised a new evolutionary map. Again, rabbis addressed the resultant issues in a forthright fashion.

In our age, the microscope is honing in even further. We are not evaluating the relationship of the earth to the rest of the universe, nor the relationship of man to the rest of the earth's creatures; no, we are exploring the very definition of man him (or her) self—the genetic map. What defines a human being? When does life begin? As in the past, today's rabbinic authorities are addressing these complex questions and producing pragmatic, life-affirming answers. The halachic map is neither new nor subject to change, though its use for navigation through uncharted waters, such as stem cell research and cloning, does require expertise.

Today a fertilized egg can be grown in the laboratory and subsequently destroyed in order to harvest its stem cells. These stem cells, potent forms of undifferentiated human tissue, may have the potential to cure many forms of devastating disease and save human lives. But while the saving of life is paramount in the rabbinic legal code, and most laws can be violated to achieve this goal, the prohibition of homicide is one notable exception. The crucial question, then, is this: Is the fertilized egg considered human life, such that destroying it in order to harvest its stem cells is tantamount to homicide?

Applying traditional talmudic methodology, let us answer a question with a question. May one violate the Sabbath to preserve the existence of a pre-embryo? We know that the Sabbath may be violated to save a human life, or even to save a potential life, as in the case of a fetus in-utero. (The distinction between life and potential life is a crucial one; rabbinic law permits abortion to save a mother's life, because the fetus in-utero is not considered a human life but only a potential life.) If the answer is yes, the Sabbath may be violated to save the pre-embryo, then it has at least the status of potential life. In fact, however, the answer

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is no—according to most contemporary rabbinic authorities, one may not violate the Sabbath to preserve the pre-embryo. And since, as the Sabbath test shows, the pre-embryo does not have the status of even potential life, it may be concluded that its use for medical research, with the potential to aid in the cure of widespread human suffering, is not only permitted but laudatory. One should treat the pre-embryo with respect, and not wantonly destroy it. It is human tissue. But it is not human life.

If use of the pre-embryo for research is allowed according to rabbinic law, may one use cell nuclear transfer — that is, cloning — to create new embryos for research purposes as well? Although existing stem-cell lines may be sufficient for current research needs, as some cloning opponents argue, it is possible in theory that the combination of stem-cell research and cloning technology could produce tissue or organs for life-saving transplantation without the need for taking life-long dangerous medications. The scientific benefit would be great. The question is whether this practice would cross a moral red line, as many ethicists have argued.

Rather than assume the answer to be no, we must ask honestly whether there is a reason, legal or otherwise, to prohibit cloning under rabbinic law. Cells are manipulated in the laboratory to produce tissue for potential clinical use. No life, or even potential life, is generated or destroyed in the process according to rabbinic law. Implantation of the cloned embryo, or reproductive cloning, is another matter, since this generates potential or future life, and there are reasons to prohibit such technology for scientific, ethical, psychological and legal reasons.

It has been argued that if therapeutic cloning is allowed, reproductive cloning is sure to follow. By that logic, we should ban all forms of cloning. However, it is important to differentiate between moral permissibility and enforceability. Must we sacrifice the great promise of therapeutic cloning for the slight possibility of aberrant reproductive cloning?

According to Jewish tradition, there existed a certain Book of Medicines in the time of the biblical King Hezekiah. It was said to contain the cures to all forms of human disease. For a variety of reasons, the king felt compelled to seize the book and bury it, effectively burying the cures with it. We are now on the verge of opening a new book of cures with stem-cell and cloning technology. This book, like its predecessor, may contain the cures to many human diseases. Perhaps the time has come to rewrite the Book of Medicines

Rabbi Edward Reichman is Assistant Professor of Philosophy and History of Medicine at the Albert Einstein School of Medicine of Yeshiva University and Assistant Professor of Emergency Medicine at Montefiore Medical Center. He was a member of the Orthodox Union-Rabbinical Council of America joint working group on cloning research, Jewish law and public policy, which issued a recommendation last March in favor of permitting therapeutic cloning.

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Ms. Jackson Lee. Mr. Chairman?

Chairman Sensenbrenner. The gentlewoman from Texas, Ms. Jackson Lee, for what purpose do you seek recognition?

Mr. NADLER. And I yield back.

Ms. Jackson Lee. To strike the last word, Mr. Chairman.

Chairman SENSENBRENNER. The gentlewoman is recognized for 5 minutes.

Ms. Jackson Lee. Thank you, Mr. Chairman.

This is a journey well-traveled. Let me make it perfectly clear that the quack-like, circus-like presentations of the last couple of months, with the suggestion that there are hidden clone babies all over the Nation was an unpleasant experience. It was not enhancing to the needs of science, medical research. To my knowledge, the cloned baby or babies, as has been noted, have yet to be produced. The presentations were unscientific, at best, circus-like more often.

We should, as a collective body, with the responsibilities of upholding the Constitution, abhor that and pass legislation that denies that. We tried to get that consensus and understanding in the last session when we reviewed this very same legislative initiative. Unfortunately, we come again without the wisdom of the many, many victims who have been helped by stem cell research; the many physicians and scientists who are doing straight, direct and effective research around the Nation, who are begging us to allow them to continue to do research to save lives.

Specifically, I rise to support the Zoe Lofgren amendment, which clearly is precise, and distinctive and understandable. It exempts therapeutic cloning of stem cells for research into some of the most horrific injuries and disabling diseases. There are well-known personalities that all of us have seen who have spent most of their lives, since their terrible injury, trying to educate us on what the value of stem cell research means.

Where we go today is an insult to them and a threat to their lives because the legislation will not allow us to contain it for what we want to contain it for, and that is to suggest to the world that this Congress stands against human cloning, to stand on the values and the principles of this country and human dignity, but yet we mix and match and undermine.

And I believe that the Zoe Lofgren legislation or amendment, clearly enunciating that reproductive cloning is wrong and should be banned, we could not get more obvious than that, suggesting that this legislation, however, hampers research, why don't we have an opportunity to have an array of doctors here from all walks of life expressing to us how important this therapeutic research is to their work?

I will have to leave this hearing because I am a few doors away in the Senate dealing with the tragedy of the Columbia seven, men and women who were willing to offer their lives, sacrifice their lives so that enormous research could be done in space to save our lives in diabetes and other areas, of course—diabetes, stroke, heart disease, cancer. And it seems to me that we do a disservice to those brave souls willing to sacrifice their lives for research that would help us by not passing this amendment that gets us squarely on the point, and that is the point that we abhor, that we find intolerable and illegal human cloning, but that we want therapeutic stem cell research to go forward.

I would rise enthusiastically to support her amendment as I leave, and I also want to put on the record that I support the Scott amendment, the Lofgren-Nadler and Schiff, even though I will not be here, and of course I know that the votes have not been taken, and I oppose final passage.

I would be happy to yield to the distinguished gentlelady from

California.

[The prepared staement of Ms. Jackson Lee follows:]

SHEILA JACKSON LEE

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Shula Judantie

#### STATEMENT BY

# CONGRESSWOMAN SHEILA JACKSON LEE MARK-UP OF H.R. 534, THE HUMAN CLONING PROHIBITION ACT OF 2003

FEBRUARY 12, 2003,

I thank Chairman Sensenbrener and Ranking Member
Conyers for holding this markup on an important public policy
matter and what many would call cutting edge scientific issue:
human cloning.

We have not held hearings in which we discussed the ethics of cloning and legislation proposals to impose federal control on the cloning process. Yet, today we will vote on the Human Cloning Prohibition Act of 2003, HR 534, previously introduced in

the  $107^{th}$  Congress as HR 2505, as well as proposed alternatives to this bill.

Cloning is a fascinating, promising issue but one that remains to be more fully explored. The scientific community in this field is still in its infancy. It is crucial that Congress carefully consider all options regarding this issue before it proceeds. We must carefully balance society's need for lifesaving scientific research against the numerous moral, ethical, social and scientific issues that this issue raises.

It is generally accepted that the majority of Americans are not yet comfortable with the production of a human clone. The legal, ethical, physical and psychological implications of such an act are not yet fully understood. The existence of these unresolved questions trumps any real or perceived need to create a cloned human being. We do not yet know the long-term health risks for a cloned human being, nor have we even determined what the rights

of a clone would be as against the person who is cloned or how either would develop emotionally. Mr. Chairman, we do not seem ready to start down the road of cloning.

What we can accept as a useful and necessary practice, however, is the use of the cloning technique to conduct embryonic stem cell research. This work shows promise in the effort to treat and even cure many devastating diseases and injuries, such as sickle cell anemia, spinal cord damage and Parkinson's disease through valuable stem cell research. This research also brings great hope to those who now languish for years or die waiting for a donor organ or tissue. Yet just as we are seeing the value of such research, there are those among us who would seek not only to stop this research, but also to criminalize it. We must pause for a moment to consider what conduct should be definitely criminalized.

I applaud the intent of HR 534, but I have serious concerns about it. HR 534 would impose criminal penalties not only on those who attempt to clone for reproductive purposes, but also on those who engage in research cloning to expand the boundaries of useful scientific knowledge and even those who ship or receive a product of human cloning. I am also concerned about the possible effect on the treatment and prevention of infertility and research into new contraceptive technologies.

In 1997, President Clinton ordered the National Bioethics
Advisory Commission to undertake a study on the ethics of human
cloning. The Commission concluded that because of safety
concerns, at this time it is morally unacceptable to attempt to create
a child by reproductive cloning, and called for federal legislation to
ban the practice. However, it explicitly noted that the question
should not yet be resolved permanently. If this legislation were to
pass it is critical to include a sunset clause to ensure that Congress
review the issue after a certain period of years.

HR 534 would make permanent the moratorium on human cloning. Those who support the bill state that we must do so because we do not fully understand the ramifications of cloning and that allowing even cloning for embryonic stem cell research is a slippery slope into reproductive cloning. I maintain that we must study what we do not know. The very fact that there was disagreement among the witnesses who spoke before us indicates that there is substantial need for further inquiry. We would not know progress if we were to criminalize every step that yielded some possible negative results along with the positive.

A reasonable alternative to HR 534 may include a five-year moratorium on cloning intended to create a human life, instead of permanently banning it. We could still permits scientific research, including embryonic stem cell research, prohibiting only importing of clones produced for reproductive purposes. I also encourage legislation that would require that the federal government conduct further study to review and evaluate what is known about the

differences and consequences of embryonic, fetal and adult stem cell research and would evaluate the need for any legislation. I also believe that we should provide an exemption for embryonic cloning for the purpose of creating a racially diverse stem cell line.

Whatever action we take, we must be careful that out of fear of remote consequences we do not chill valuable scientific research, such as that for the treatment and prevention of infertility or research into new contraceptive technologies. The essential advances we have made in this century and prior ones have been based on the principles of inquiry and experiment. We must tread lightly lest we risk trampling this spirit. Consider the example of Galileo, who was exiled for advocating the theory that the Earth rotated around the Sun. It is not an easy balance simultaneously to promote careful scientific advancement and protect ourselves from what is dangerous, but we must strive to do so.

Mr. Chairman, we must think carefully before we vote on this legislation, which will have far reaching implications on

scientific and medical advancement and set the tone for Congressional oversight of the scientific community. If I were present to vote I would like to note for the record that I would have voted yea for the Scott amendment on importation and yea on the Lofgren amendment on reproductive cloning. Thank you.

Ms. LOFGREN. Thank you for yielding.

I would just like to note we have focused quite often on the needs of those who are suffering from illnesses and the need for their cures that may come through therapeutic cloning solutions. However, the gentlelady from Texas has touched on another issue which also deserves our attention, and that is the role of the United States leading the world in science and in research.

And I think it's worth pointing out that the cutting-edge research undertaken by the University of California in San Francisco has now been moved off-shore to Great Britain because of the threats that those scientists felt from the actions that the Administration and this Congress is either taking or discussing.

I think it's important that we do not become the scientific backwater of the world because we have established a theocracy here.

Chairman SENSENBRENNER. The gentlewoman's time has expired.

Mr. Schiff. Mr. Chairman?

Chairman SENSENBRENNER. For what purpose does the gentleman from California seek recognition?

Mr. Schiff. Move to strike the last word, Mr. Chairman.

Chairman Sensenbrenner. The gentleman is recognized for 5 minutes.

Mr. Schiff. Mr. Chairman, I had intended to offer an amendment in the nature of a substitute which mirrors the Feinstein-Hatch bill in the Senate, but as this amendment is substantially similar to what my colleague from California, Zoe Lofgren, has offered, in the interest of time and because my amendment in the nature of a substitute is rather lengthy, and I would not want to indulge the Committee to have to read the entire amendment, I will waive the offering of that amendment and instead voice my support for my colleague's amendment from California.

I'd like to use my time to not repeat some of the ground that's been covered, but rather address some of the points that the opposition to this amendment has made. After all, both the base bill and the amendment do much the same thing in that they ban cloning for reproductive purposes. The only area of substantial distinction is whether we should ban somatic cell nuclear transfer for therapeutic purposes, and there are basically three arguments that are made against this amendment and against this principle.

The first is that other stem cells will do. We don't need to use somatic cell nuclear transfer. We can use other stem cells. We can use adult stem cells. The fact of the matter is that at the present state of the science, there is no adequate substitute for this research, important research and therapeutic technique, and why is that true? Because when you transfer the nuclear material into the egg from the donor, it has the donor's genetic information, and that means that it won't be rejected by the donor.

So we have, really, a choice between two lines of treatment; one, where we don't transfer the nuclear material, and it is likely to be rejected, and you have to use very destructive immunosuppressant drugs; or, two, you can use the nuclear transfer technology, and it won't be rejected because basically the body believes it is from the same body as the donor.

This is an enormous advantage. Now, it may be that science catches up with us. It may be that through research with somatic

cell nuclear transfer that we learn how we can differentiate adult stem cells so that this is no longer necessary, but we can't get there from here without this important scientific research. So other stem cell techniques will not do. They are not an adequate substitute, and I'd like to introduce in the record the statement of 40 Nobel Laureates in Science supporting this Feinstein-Hatch analogous legislation.

Chairman SENSENBRENNER. Without objection, the statement will be included in the record.

[The information referred to follows:]



NATIONAL OFFICE: 8120 Woodmont Avenue, Suite 750 Bethesda, Maryland 20814-2762 TEL: 301/347-9300 FAX 301/347-9310 E-MAIL aschinfo@asch.org www.asch.org

Two National Academy of Sciences expert committees, as well as noted national and international organizations, have evaluated current scientific and medical information and have concluded that cloning a human being using the method of nuclear transplantation cannot be achieved safely. Such attempts in other mammals often have catastrophic outcomes. Furthermore, virtually nothing is known about the potential safety of such procedures in humans. Consequently, there is widespread and strong agreement that an attempt to clone a human being would constitute unwarranted experimentation on human subjects and should be prohibited by legislation that imposes criminal and civil penalties on those who would implant the product of nuclear transplantation into a woman's uterus.

Unfortunately, some legislation, such as that introduced by Senator Brownback (R-KS) would foreclose the legitimate use of nuclear transplantation technology for research and therapeutic purposes. This would impede progress against some of the most debilitating diseases known to man. For example, it may be possible to use nuclear transplantation technology to produce patient-specific embryonic stem cells that could overcome the rejection normally associated with tissue and organ transplantation. Nuclear transplantation technology might also permit the creation of embryonic stem cells with defined genetic constitution, permitting a new and powerful approach to understanding how inherited predispositions lead to a variety of cancers and neurological diseases such as Parkinson's and Alzheimer's diseases

A critical element of the Brownback bill would prevent the importation into the United States of medical treatments developed in other parts of the world using nuclear transplantation. It seems unbelievable that the United States Senate would deny advanced medical treatment to millions of suffering Americans because of an aversion to a technology that was used in its development.

By declaring scientifically valuable biomedical research illegal, Senator Brownback's legislation, if it becomes law, would have a chilling effect on all scientific research in the United States. Such legal restrictions on scientific investigation would also send a strong signal to the next generation of researchers that unfettered and responsible scientific investigation is not welcome in the United States.

We, the undersigned, urge that legislation to impose criminal and civil sanctions against attempts to create a cloned human being be enacted. We also oppose strongly any legislation that would prohibit or impede the scientifically legitimate, responsible use of nuclear transplantation technology for research and therapeutic purposes. Similarly, any attempt to prohibit the use of therapies in the United States that were developed with the aid of nuclear transplantation technology overseas denies hope for those seeking new therapies for the most debilitating diseases known to man.

Sidney Olto

Sidney Altman Sterling Professor of Biology Yale University Nobel Prize in Chemistry, 1989

Smutt J. ann

Kenneth J. Arrow Professor of Economics and

Professor of Operations Research, Emeritus

Stanford University

Nobel Prize in Economics, 1972

Julius axelrod

Julius Axelrod Scientist Emeritus National Institutes of Health Nobel Prize in Physiology or Medicine, 1970

David Baltimore

Jul Bry

President and Professor of Biology California Institute of Technology Nobel Prize in Physiology or Medicine, 1975 Ford Berg

Paul Berg

Cahill Professor of Cancer Research and Biochemistry, Emeritus Director, Beckman Center for Molecular & Genetic Medicine, Emeritus Stanford University School of Medicine Nobel Prize in Chemistry, 1980

J. Michael Bishop

University Professor and Chancellor University of California, San Francisco Nobel Prize in Physiology or Medicine, 1989

Thomas R. Cel

Thomas R. Cech Distinguished Professor University of Colorado, Boulder Nobel Prize in Chemistry, 1989

Atauly Cohen

Stanley Cohen Distinguished Professor of Biochemistry, Emeritus Vanderbilt University

Nobel Prize in Physiology or Medicine, 1986

Elias James Corey Sheldon Emery Research Professor of Chemistry

Harvard University

Nobel Prize in Chemistry, 1990

Eleas Jamas Coray



Johann Deisenhofer Virginia and Edward Linthicum Distinguished Chair in Biomolecular Science Regental Professor University of Texas Southwestern Medical Center at Dallas Nobel Prize in Chemistry, 1988

Remarks Guller

Renato Dulbecco Distinguished Research Professor President Emeritus The Salk Instistute Nobel Prize in Physiology or Medicine, 1975

Elmonthe for My

Edmond H. Fischer Professor, Emeritus of Biochemistry University of Washington Nobel Prize in Physiology or Medicine, 1992

Jerone I. Friedman

Jerome I. Friedman Institute Professor Massachusetts Institute of Technology Nobel Prize in Physics, 1990

Walter Gilbert

Walter Gellet

Carl M. Loeb University Professor The Biological Laboratories Harvard University Nobel Prize in Chemistry, 1980 Alfred G. Gilman

Regental Professor and Chairman Raymond and Ellen Willie Distinguished Chair in Molecular Neuropharmacology Director, Alliance for Cellular Signaling
Chairman, Department of Pharmacology
University of Texas Southwestern Medical Center
Nobel Prize in Physiology or Medicine, 1994

Donald A. Glaser Professor of Physics and Neurobiology University of California, Berkeley Nobel Prize in Physics, 1960

Dwold & Deren

Joseph L. Goldstein Regental Professor

Department of Molecular Genetics

University of Texas Southwestern Medical Center

Nobel Prize in Physiology or Medicine, 1985

Paul Greengard Vincent Astor Professor

Hard Creenzard

Laboratory of Molecular and Cellular Neuroscience

The Rockefeller University

Nobel Prize in Physiology or Medicine, 2000

Lee Hartwell

Lee Hartwell
President and Director
Fred Hutchinson Cancer Research Center
Professor, Department of Genome Sciences
University of Washington School of Medicine
Nobel Prize in Physiology or Medicine, 2001

Budley Herochlack

Dudley Herschbach Baird Professor of Science Department of Chemistry and Chemical Biology Harvard University Nobel Prize in Chemistry, 1986

Tim Hunt Principal Scientist

Cancer Research UK Nobel Prize in Physiology or Medicine, 2001

Jama Karle

Jerome Karle Chief Scientist Laboratory for the Structure of Matter Naval Research Laboratory Nobel Prize in Chemistry, 1985

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Arthur Kornberg Emma Pfeiffer Memer Professor Emeritus Professor of Biochemistry Stanford University School of Medicine Nobel Prize in Physiology or Medicine, 1959 En & the

Edwin G. Krebs
Professor Emeritus, Senior Investigator Emeritus
Perostment of Pharmacology, Howard Hughes M

Department of Pharmacology, Howard Hughes Medical Institute University of Washington School of Medicine Nobel Prize in Physiology or Medicine, 1992

Can M Rederman

Leon M. Lederman Pritzker Professor of Science Illinois Institute of Technology Nobel Prize in Physics, 1988

Edward & Dellis

Edward B. Lewis Thomas Hunt Morgan Professor of Biology, Emeritus California Institute of Technology Nobel Prize in Physiology or Medicine, 1995

Allian V Sepsemb

William N. Lipscomb Abbot and James Lawrence Professor, Emeritus Department of Chemistry and Chemical Biology Harvard University Nobel Prize in Chemistry, 1976

Feid Mmse

Ferid Murad Professor and Chairman Department of Integrative Biology, Pharmacology and Physiology University of Texas at Houston Nobel Prize in Physiology or Medicine, 1998

Marshall Nirenberg Chief, Laboratory of Biochemical Genetics National Heart, Lung & Blood Institute National Institutes of Health Nobel Prize in Physiology or Medicine, 1968

Marshell Nicolan

Paul Nurse

Sir Paul Nurse Director-General (Science) Cancer Research UK Nobel Prize in Physiology or Medicine, 2001

Burton Richter

Paul Piggot Professor in the Physical Sciences Director, Stanford Linear Accelerator Center, Emeritus Nobel Prize in Physics, 1976

Reland F. Robert

But Rulli

Richard J. Roberts Research Director New England Biolabs Nobel Prize in Physiology or Medicine, 1993

Phillip A. Sharp Institute Professor Director, McGovern Institute

Massachusetts Institute of Technology

Nobel Prize in Physiology or Medicine, 1993

Hamilton O. Smith

Senior Director of DNA Resources

Hamilton O. Smith

Celera Genomics

Nobel Prize in Physiology or Medicine, 1978

Robert M. Solon

Robert M. Solow Institute Professor Emeritus Massachusetts Institute of Technology Nobel Prize in Economics, 1987

E Donal Phonos

E. Donnall Thomas Professor of Medicine, Emeritus University of Washington Member, Fred Hutchinson Cancer Research Center

Hassel Virine

Harold Varmus

President, Memorial Sloan Kettering Cancer Center Former Director, National Institutes of Health Nobel Prize in Physiology or Medicine, 1989

Nobel Prize in Physiology or Medicine, 1990

Lancis Wot

James D. Watson President, Cold Spring Harbor Laboratory Director, National Center for Human Genome Research, NIH, 1989-1992

Nobel Prize in Physiology or Medicine, 1962

Took Viul

Torsten Nils Wiesel The Rockefeller University, President Emeritus Nobel Prize in Physiology or Medicine, 1981

Robert W. Wilson Senior Scientist Harvard-Smithsonian Center for Astrophysics Nobel Prize in Physics, 1978

Mr. Schiff. Second, the argument is made by my colleagues that this will increase the likelihood of abuse, that law enforcement won't be able to tell, when they go into a laboratory, where the nucleus has been transferred, where it hasn't, and this will impede law enforcement.

Well, by this argument, we should shut down all fertility clinics because you can conduct this kind of work in any fertility clinic that does in vitro fertilization. No one would suggest that we ought to prohibit fertility treatments because of potential abuse. That is

simply not a compelling argument.

The only argument that is compelling at all is the argument that life has begun, and on this point, each of us brings into this Committee, and none of us are going to be persuaded by the other, a philosophical moral view about when life begins. But I think the reason why the Senate has bipartisan support for this therapeutic exception is that, while we cannot agree when life begins, many of us can, nonetheless, agree that that is a very personal, moral decision, that we should not use the coercive power of the Government to decide for others that essential question. That is not susceptible to a scientific answer.

So should we use the coercive effect of the Government, the criminal penalties of the Government to say that because I feel or someone else feels that life begins at a certain point that we will prevent those who feel differently from obtaining treatment that

may save their lives?

Now, I don't happen to think that life begins with a somatic cell nuclear transplant. At one level, you could say that a living cell is life, and life begins even before conception or before nuclear transfer, but even if I felt otherwise, I would agree, I think, with Senator Hatch and many who share that view, but nonetheless feel that the coercive power of the Government should not be used to decide that question for others in a way that inhibits their ability to receive needed treatment.

Those that do feel that way can take a principled stand say, "I won't use the benefit of any of this research that has utilized this scientific research. I won't accept it because of the way it was generated." That's a principled view, but that's different from saying, "I will deny to all others who see this question differently the ability to get treated for the diseases that they suffer."

And so I urge support for Zoe Lofgren's amendment. I urge support for the Senate bill introduced by Senators Hatch and Fein-

stein.

I yield back the balance of my time.

Chairman Sensenbrenner. The gentleman's time has expired.

Mr. Pence. Mr. Chairman?

Chairman SENSENBRENNER. For what purpose does the gentleman from Indiana seek recognition?

Mr. Pence. I move to strike the last word, Mr. Chairman.

Chairman Sensenbrenner. The gentleman is recognized for 5 minutes.

Mr. PENCE. Thank you, Mr. Chairman.

I want to express my respect and appreciation for the authors of this amendment and the sincerity of their purpose. The gentlelady from California and I got to spend some time together on September 11th, 2001, in which we forged a friendship, and I have since come to appreciate her compassion and her deep commitment to the betterment of the lives of American families, and so I don't question the intention, Mr. Chairman, of the authors of this amendment, but I do question it's wisdom.

We have heard reference to opposition to this amendment and opposition to therapeutic cloning as being an example of the advent of theocracy in America or the advent of imposing religion through Government power, and I would rather offer that humility before even nascent human life is at the very center of what has been unique and special about Western civilization, that whenever, as the gentleman from California just alluded, whenever one slices this issue of when life begins, there is no question but that we are dealing, at minimum, with nascent human life.

And I am of a mind, as, in my view, has been the overwhelming majority of intellectual thinking throughout the history of Western civilization, that consolidated power, Government power, the power of individuals acting in a collective way ought to back ever and always slowly away from the awesome power of human life, that history is pockmarked, sadly, with hundreds, if not thousands, of instances of formal Government power intruding itself on even nascent human life and trampling the rights of individuals. There is almost no Government action of which we can be more confident, with the study of 5,000 years-plus of recorded human history, that governments, if given the ability to trample on human beings, trample on human beings.

And so I would oppose this amendment simply on the basis of counseling humility, counseling respect for moral traditions and offering very sincerely that I don't believe this is a question of religion, per se, but it is a question that we're, and it's a very unique thing to see the agreement on this panel on any issue, leaving aside the issue of human cloning, where we all agree, but to hopefully, Mr. Chairman, produce a bill today which would not include an exception that would, in my humble opinion, nullify much of what we hope to accomplish in this body in putting a strong and humble stand down of respect for nascent human life.

I vield back.

Chairman SENSENBRENNER. For what purpose does the gentlewoman from Wisconsin seek recognition?

Ms. BALDWIN. Mr. Chairman, I move to strike the last word.

Chairman SENSENBRENNER. The gentlewoman is recognized for 5 minutes.

Ms. BALDWIN. Thank you, Mr. Chairman.

Speaking in support of the amendment offered by Congresswoman Lofgren and urge its acceptance by this Committee. It would exempt research for therapies derived from embryonic stem cells from the ban proposed under H.R. 534.

This research is a critical tool in the battle against Parkinson's disease, Alzheimer's, diabetes, spinal cord injuries and other debilitating and sometimes life-ending conditions. We know that scientists have made tremendous strides in recent years with technologies that were not even imagined only a few years ago, and much of this research is very exciting in its potential to heal the sick and to improve the quality of life for patients around the world.

I am hopeful that in the coming months and years, researchers will learn more about the unique properties of embryonic stem cells, what they can do for patients with debilitating diseases.

I'm proud also that a number of the existing stem cell lines that are eligible for use in federally supported research were developed in the congressional district that I represent, and I strongly support the research that scientists at the University of Wisconsin are

advancing.

Medical research focuses on preventing disease, curing disease, slowing the progress of disease, lengthening life and easing pain. Cloning for the purposes of medical research is not the same as cloning for the purposes of reproduction. I am opposed to the latter, I think that is the consensus, but I believe that if there is a possibility that therapeutic cloning could provide a cure that would save the lives of millions of patients who suffer every day with terrible diseases, then we should do everything we can to encourage this research.

I urge my colleagues to support this amendment and yield back my remaining time.

Chairman Sensenbrenner. The question is on the Lofgren

amendment.

Those in favor will say aye.

Opposed, no.

The noes appear to have it. The noes have it. Ms. LOFGREN. I would request a recorded vote.

Chairman SENSENBRENNER. A recorded vote is requested and will be granted, and pursuant to the provision of Committee rules, the vote on this question will be postponed.

Are there further amendments? Mr. NADLER. Mr. Chairman?

Chairman Sensenbrenner. The gentleman from New York.

Mr. NADLER. Mr. Chairman, I have an amendment at the desk, and this amendment is co-sponsored by Ms. Jackson Lee.

Chairman SENSENBRENNER. The clerk will report the Nadler-Jackson Lee amendment.

The CLERK. Amendment to H.R. 534, offered by Mr. Nadler and Ms. Jackson Lee.

"Page 4, line 16, strike the close quotation mark and the period that follows."

"Page 4, after line 16, insert the following:"

"(e) Exceptions——"

Chairman SENSENBRENNER. Without objection, the amendment is considered as read, and the gentleman is recognized for 5 minutes. [The amendment follows:]

### AMENDMENT TO H.R. 534 OFFERED BY M.r. CONTEST AND MACKSON

Page 4, line 16, strike the close quotation mark and the period that follows.

Page 4, after line 16, insert the following:

- 1 "(e) EXCEPTIONS.—The prohibitions of this section
- 2 do not apply to the transfer of nucley from somatic cells
- 3 into unfertilized eggs to derive embryonic stem cells for genetically diverse embryonic stem
- 5 cell lines.".



Mr. NADLER. Thank you, Mr. Chairman.

Mr. Chairman, this amendment would address a very serious problem arising from the intersection of this legislation and President Bush's limitations on stem cell research. We all know that the President issued an order limiting stem cell research to the 70 or

so cell lines in existence as of August 9, 2001.

This legislation takes that order and sets it in stone with regard to embryonic stem cells, but one problem is that of the 70 lines grandfathered by President Bush's order, only a handful, certainly less than 10, in fact, are usable scientifically. One problem with the small number of lines is that it in no way represents the genetic

diversity of our population.

The lines which are in existence are all from either Singapore, Scandinavia, India and the University of Wisconsin. They are all derived from people who are of a sufficient level of affluence to be seeking in vitro fertilization. Not surprisingly, there are few, if any, cell lines derived, for example, from African Americans. The researchers using these cells have told us so, among them Professor Irving Weissman of the Stanford University Stem Cell Institute, and the chair of the National Academy of Sciences Panel on Stem Cells has informed us of this fact.

This means that it is next to impossible to use the stem cell lines that are in existence that were grandfathered under the President's order to research or potentially to cure diseases which are particularly prevalent in people of particular racial or ethnic groups, such as, for example, sickle cell diseases in African Americans or Tay-

Sachs disease for Ashkenazic Jews.

The Institute of Medicine study explains in detail that the fewer cell lines that are available to researchers the lower the genetic diversity they represent. As a result, Ms. Jackson Lee and I are offering an amendment which would amend the bill to permit additional stem cell research solely for the purpose of creating genetically diverse stem cell lines for different population groups so that all population groups may be hopeful of cures for diseases which may be particularly prevalent in their genetic population group.

We already have a digital divide. The last thing we need is a biotech divide. This amendment would help make sure that the research that is being done is not done in any sort of discriminatory basis, not with any intent, but in effect that's what the President's order would do, and if codified by this bill would do because there is simply not genetic diversity in those fewer than 10 stem cell

I hope Members on both sides of the aisle would join in approving this common-sense amendment.

Thank you, Mr. Chairman. I yield back.

Mr. COBLE. Mr. Chairman?

Chairman Sensenbrenner. The gentleman from North Carolina, Mr. Coble?

Mr. Coble. Mr. Chairman, I speak in opposition to the amend-

Chairman Sensenbrenner. The gentleman is recognized for 5

Mr. Coble. This is popularly known as the SCNT approach. This amendment, Mr. Chairman and Members, would add a provision to the bill which, in effect, states that nothing in this act shall prohibit the use of somatic cell nuclear transfer to produce stem cells.

I oppose the amendment for two reasons. Number one, the amendment is unnecessary. There is absolutely nothing in this bill that would prohibit stem cell research that does not require the cloning of humans. The language of the bill specifically states that nothing shall restrict areas of scientific research not specifically prohibited by this bill, including research in the use of nuclear transfer or other cloning techniques used to produce molecules, DNA cells, other than human embryos, tissues, organs, plants or animals other than humans.

The second reason I oppose the amendment is that I believe the language is too broad. The amendment cites the medical procedure known as somatic cell nuclear transfer, which is the procedure by which cloned human embryos are created. It may be unintentional, but I believe that the language could be interpreted to create a loophole for the production of cloned human embryos from stem cell research purposes.

If it is intentional, then I think that what the sponsor may be trying to create is an exception to the bill for what has been called therapeutic cloning. This would amount to a partial ban on human

cloning that I believe would be unenforceable.

As I have stated earlier, Mr. Chairman and Members, once cloned embryos are produced and available in laboratories, it is virtually impossible to control what is done with them. In his testimony last year, and I have said this before, but I want to emphasize it, the Department of Justice spokesman said that enforcing such a limited ban would put law enforcement in the unenviable position of having to impose new and unprecedented scrutiny over physicians and fertility clinics and/or research facilities to ensure that only fertilized embryos were being transferred to would-be mothers and not cloned embryos.

Creating cloned human children, as I said earlier, and I apologize for repeating it, but it begins by producing cloned human embryos. And if we want to prevent cloned children, we need to, by necessity, prevent cloned embryos, and I urge my colleagues to—

Mr. NADLER. Will the gentleman yield?

Mr. Coble. Yes, sir.

Mr. Nadler. Thank you. The gentleman partially misstates the amendment and partially understands it correctly. Let me just

clarify.

This, indeed, would create, I won't call it a loophole, I will call it an exception, and permit the cloning of single cells for the purpose of generating stem cells, but not for the purpose of generating any stem cells—that was a prior amendment—for the purpose of generating only stem cells necessary to have genetically diverse embryonic cell lines, and that's what the amendment does, and it was intentional, and that's exactly the purpose of the amendment.

And I would simply add one other thing. Again, I must state that if the Justice Department is worried about how to enforce whether a clinic is implanting in a woman's uterus a cloned embryo, as opposed to a noncloned embryo, they have to be just as worried about, and have just as much intrusive, not more/not less intrusion to look into the lab to see if they're creating a cloned embryo, whether

therapeutic cloning is legal or whether therapeutic cloning is illegal

The key act is implantation in the uterus. You have to check that whether you adopt one version of this bill or the other version of this bill. There's no difference there.

I yield back. I thank the gentleman, and I yield back.

Chairman SENSENBRENNER. Does the gentleman from North Carolina yield back?

Mr. COBLE. Yes, I yield back, Mr. Chairman.

Mr. BACHUS. Mr. Chairman?

Chairman SENSENBRENNER. For what purpose does the gentleman from Alabama seek recognition?

Mr. Bachus. To oppose the amendment.

Chairman SENSENBRENNER. The gentleman is recognized for 5 minutes.

Mr. Bachus. Mr. Chairman, Mr. Nadler, in advocating for the previous amendment, read a statement, and I think when he read it, I think one thing it does highlight for both sides what the issue is. What he quoted from a few minutes ago was *The Washington Post*, an article by Alan Cooperman, March 13, 2002. And what Mr. Nadler read, and let me read it again because it basically distills what this whole debate is about, and you have to fall out on one side or the other because we're going to have to vote in a few minutes on this amendment and on the previous one.

It says, "The Nation's largest orthodox Jewish organizations declared their support yesterday for allowing scientists to clone human embryos for medical research, breaking with some conservative Christian groups on a topic of hot debate in the Senate."

I would agree with Mr. Nadler that, you know, we don't have to, I mean, it's not a religious argument, it's just we could actually read that. Another way to read it is some organizations declared their support yesterday for allowing scientists to clone human embryos for medical research, breaking with other groups on a topic of hot debate. I mean, one side or the other, that's what—

Now, let me quote another quote out of this article, because this is the essence of all of this.

"The approach endorsed yesterday by," one of the groups, the head of that organization said, and here is the whole issue, "We must be careful to distinguish between cloning for therapeutic purposes which ought to be pursued and cloning for reproductive purposes which we oppose."

That's absolutely what we're talking about here. Now, some of us don't believe that scientists should clone human embryos for any purpose. Now, that's how I'm going to vote. Others believe that scientists ought to be able to, in his words, "clone human embryos for modical research."

medical research."

That's what we're going to be voting on. Some people say we can distinguish, and there's a difference, and you know you can be for one, but there's a distinction between cloning for therapeutic purposes, which is okay, and cloning for reproductive purposes, which we oppose.

I am going to vote, because I think that cloning for, if cloning is wrong, it's wrong for any purpose. But I can, I mean, I respect the gentleman's opinion that you can say that cloning for some purposes is okay, cloning of human embryos, cloning for other purposes.

poses is morally wrong. I disagree. I just don't see the distinction, and that's what we're going to be voting on.

Mr. NADLER. Would the gentleman yield?

Mr. BACHUS. Whether or not we will allow scientists, in the words of The Washington Post or this group, whether we're going to allow scientists to clone human beings for medical research or for whatever other purposes. I'm opposed to it.

Mr. NADLER. Would the gentleman yield?

Mr. Bachus. I would yield.

Mr. Nadler. I appreciate the gentleman yielding, and I agree with the gentleman that that is the crux of the debate here. The point I was trying to make, let me read, again, one sentence from the same article. This is right after the one that you read before at the top of the page. His name is Edward Reichman, "an orthodox rabbi and physician," and so forth, "said the Jewish position, the Jewish religious position is that a 'fertilized embryo in a petri dish does not have the same status of human life,' and if such an embryo can be used to cure diseases and save lives, 'that is something we would welcome with open arms."

The nub of this whole question is does one consider a fertilized embryo in a petri dish as a human life or not? If one does, then obviously cloning in order to generate an embryo and then a cell line which will be destroyed is murder. If one does not think that's a human life, then it's a scientific procedure which may be a good

thing to develop cures.

So the nub of the question is does an embryo in a petri dish have the status of human life. The point or not. The point I was making before is that you could name half a dozen religious groups that say, yes; you can name half a dozen religious groups, including the one that happened to be in this article, that say, no. And my point is that that's a religious question, really. Science can give you no answer to it. You could debate it endlessly in science. And a religious view should not be, in my view, imposed on people of all religious views in this society by Government, and that's the point why I oppose this bill.

Chairman Sensenbrenner. The time-Ms. LOFGREN. Would the gentleman yield?

Chairman Sensenbrenner. The time of the gentleman—

Mr. Bachus. Would the gentleman yield back?

Mr. Nadler. I yield back, of course.

Chairman Sensenbrenner. The time of the gentleman now has expired.

The question is on the Nadler-

Mr. NADLER. And I thank the gentleman.
Ms. Lofgren. Mr. Chairman, I move to strike the last word.

Chairman Sensenbrenner. The gentlewoman is recognized for 5 minutes.

Ms. Lofgren. I wanted, I don't know that I'll use the entire 5 minutes, but I think, clearly, we understand the disagreements that are among us here, but I think that Mr. Nadler's amendment also draws attention to a narrower issue. As we know, there are some stem cells that currently exist that are being utilized for research purposes. The President made a large announcement about that the summer before last.

When those stem cells were devised, those researchers who were doing the lab work I don't think ever envisioned that that would be the end of it, that it was only going to be those few research opportunities, and as I understand it, as is often the case in science research, the donors of the skin cells and the like tend to be graduate students at a university.

They did not do a survey of the genetic richness of society, understanding that that would be a necessity, and so I think that you would find, at least the reports that I have written, is that those stem cells do not necessarily accommodate genetic differences that might be prevalent, although not 100 percent, in certain Asian populations or in certain African populations or, for example, Tay-Sachs, which is often a genetic defect that might be found in Jew-

ish people from the Mediterranean area.

And so what Mr. Nadler's amendment is saying is address the genetic narrowness that exists on the current stem cell panoply. I think we should go farther, as my amendment would have done, but I would hope that we could search, those of us who disagree with my amendment, and I have heard you, might sort through whether really it is fair that the full richness of American society, the genetic richness that is often connected, although not completely, with the origins of where one's family, what continent one's family originally came from would not be represented on the current stem cell lines, and therefore there would be a discriminatory result for cures that might result from even the research that the President says he approves of.

And so that is I think the specific point that Mr. Nadler is making, and I think it's a good one, and it deserves the consideration of those who even disagreed with the broader amendment that I of-

fered a while ago, and I would yield back my time.

Chairman SENSENBRENNER. The question is on the amendment offered by the gentleman from New York, Mr. Nadler.

Those in favor will say aye.

Opposed, no.

The noes appear to have it. The noes have it, and the amendment is not agreed to.

Are there further amendments?

The gentlewoman from California, Ms. Sánchez?

Ms. SÁNCHEZ. Thank you, Mr. Chairman. I have an amendment at the desk.

Chairman Sensenbrenner. The clerk will report the amendment.

The CLERK. Amendment to H.R. 534, offered by Ms. Sánchez.

Page 4, line 16, strike the close quotation mark and the period which follows.

Page 4, after line 16, insert the following:

"(e) Sunset. The prohibitions of this section do not apply to any activity occurring on——"

Chairman Sensenbrenner. Without objection, the amendment is considered as read.

[The amendment follows:]

# AMENDMENT TO H.R. 534 OFFERED BY Linda Sanchez

Page 4, line 16, strike the close quotation mark and the period which follows.

Page 4, after line 16, insert the following:

- 1 "(e) Sunset.—The prohibitions of this section do
- 2 not apply to any activity occurring on or after the expira-
- 3 tion of the 3-year period beginning on the date of enact-
- 4 ment of the Human Cloning Prohibition Act of 2003.".



Chairman SENSENBRENNER. The gentlewoman from California is recognized for 5 minutes. And before recognizing you, it is my understanding that this is the last amendment; am I correct?

The chair will state that we will vote on the postponed votes immediately after the voice vote on the Sánchez amendment. So I would ask the staff on both sides to summon the Members because we will be voting shortly.

The gentlewoman is recognized for 5 minutes.

Ms. SÁNCHEZ. Thank you, Mr. Chairman.

The proposed amendment is a sunset provision to H.R. 534, and what it allows is Congress to, after a 3-year period, to revisit the

many issues that we've been discussing today.

Research in cell technologies, including in the field of embryonic stem cells, has been described as having vast potential for medical use and for curing what we thought were incurable diseases. However, we currently know very little about the exact mechanisms of cell development or about the potential for clinical treatments using these technologies.

Given the pace of scientific research here and abroad, in 3 years, I'm sure we will likely know far more about the medical uses of

these technologies to cure diseases and save lives.

The state of scientific knowledge and medical technology is changing rapidly, and over time could make the laws that we enact today obsolete. Congress, I believe, deserves the opportunity to review this legislation after an appropriate time so that we do not make a legal change that is permanent to govern science that is constantly in flux.

In its comprehensive report on human cloning, the National Bioethics Advisory Commission recommended a sunset of a 3- to 5year range. The report called the sunset provision critical because it would guarantee that Congress would return to these issues and reconsider them in light of new scientific developments.

This amendment is a modest step to do that, and I urge the Committee's consideration for this amendment.

I yield back my time.

Chairman Sensenbrenner. The gentleman from North Carolina, Mr. Coble?

Mr. Coble. Mr. Chairman, I want to oppose the gentlelady's—Chairman Sensenbrenner. The gentleman is recognized for 5 minutes.

Mr. COBLE.—oppose the amendment offered by the gentlelady from California, and I will not take 5 minutes.

This amendment contains, as the gentlelady said, a 3-year sunset provision so that none of the prohibitions on human cloning would be in effect 3 years after enactment of the bill. I oppose the amendment because, obviously, we don't know what the status of our bio technological capabilities are going to be 3 years from now, much less 6 months or even 6 weeks from now.

So, until we're in a position to know what the future holds, I think we should avoid automatically sunsetting any legislation, certainly one of this significance.

Secondly, Congress can, as we all know, if it chooses, 3 years from now or at any point, change the law after we have had an opportunity to reexamine the issue and have sufficient knowledge to know that we are continuing to protect people from unethical ex-

perimentation procedures, and for those reasons, Mr. Chairman, I would oppose the amendment.

Chairman Sensenbrenner. Does the gentleman yield back?

Mr. COBLE. I yield back my time.

Chairman Sensenbrenner. The gentleman from Virginia, Mr. Scott. What purpose do you seek recognition?

Mr. Scott. I move to strike the last word.

Chairman Sensenbrenner. The gentleman is recognized for 5 minutes.

Mr. Scott. Mr. Chairman, I think the gentleman from North Carolina is right. We don't know what the status will be the next year or the year after that or the year after that, and that's why we need to revisit the issue, and why I support the amendment.

There is a clear consensus on cloning of—reproductive cloning for live human beings, but the research on diabetes, Parkinson's disease, Alzheimer's and others is alive and well, and we need to revisit. If this bill is to pass, we really need to revisit it, and a 3-year period would give us ample time.

This is a fast-moving area. Every day there's more news and more research, and it would be unfortunate if we locked ourselves in to a perpetual ban on this kind of research. So I would hope that the amendment from the gentlelady from California would be adopted.

I yield back the balance of my time.

Chairman Sensenbrenner. The question is on the amendment offered by the gentlewoman from California.

Those in favor will say aye.

Opposed, no.

The noes appear to have it. The noes have it, and the amendment is not agreed to.

Are there further amendments?

[No response.]

Chairman Sensenbrenner. If there are no further amendments, consideration will resume of those amendments which were debated earlier today and upon which the votes were postponed.

The votes will be taken in the following order:

First, the Scott amendment, relative to importation, upon which the noes prevailed by a voice vote;

Second, the Lofgren amendment, relative to therapeutic cloning, upon which the noes prevailed by a voice vote.

The clerk will re-report, redesignate the Scott amendment. The CLERK. Amendment to H.R. 534, offered by Mr. Scott.

Chairman Sensenbrenner. The question is on adoption of the Scott amendment.

Those in favor will, as your names are called, answer aye; those opposed, no, and the clerk will call the roll.

The CLERK. Mr. Hyde?

[No response.]

The CLERK. Mr. Coble?

Mr. Coble. No.

The CLERK. Mr. Coble, no. Mr. Smith?

Mr. SMITH. No.

The CLERK. Mr. Smith, no. Mr. Gallegly?

Mr. Gallegly. No.

The CLERK. Mr. Gallegly, no. Mr. Goodlatte?

[No response.]

The CLERK. Mr. Chabot?

Mr. Chabot. No.

The CLERK. Mr. Chabot, no. Mr. Jenkins?

Mr. Jenkins. No.

The CLERK. Mr. Jenkins, no. Mr. Cannon?

[No response.]

The CLERK. Mr. Bachus?

Mr. Bachus. No.

The CLERK. Mr. Bachus, no. Mr. Hostettler?

Mr. Hostettler. No.

The CLERK. Mr. Hostettler, no. Mr. Green?

[No response.]

The CLERK. Mr. Keller?

Mr. Keller. No.

The CLERK. Mr. Keller, no. Ms. Hart?

Ms. Hart. No.

The CLERK. Ms. Hart, no. Mr. Flake?

Mr. Flake. No.

The CLERK. Mr. Flake, no. Mr. Pence?

Mr. Pence. No.

The CLERK. Mr. Pence, no. Mr. Forbes?

Mr. Forbes. No.

The CLERK. Mr. Forbes, no. Mr. King?

Mr. KING. No.

The CLERK. Mr. King, no. Mr. Carter?

Mr. Carter. No.

The CLERK. Mr. Carter, no. Mr. Feeney?

Mr. FEENEY. No.

The CLERK. Mr. Feeney, no. Mrs. Blackburn?

Mrs. Blackburn. No.

The CLERK. Mrs. Blackburn, no. Mr. Conyers?

[No response.]

The CLERK. Mr. Berman?

[No response.]

The CLERK. Mr. Boucher?

[No response.]

The CLERK. Mr. Nadler?

Mr. Nadler. Aye.

The CLERK. Mr. Nadler, aye. Mr. Scott?

Mr. Scott. Aye.

The CLERK. Mr. Scott, aye. Mr. Watt?

Mr. WATT. Aye.

The CLERK. Mr. Watt, aye. Ms. Lofgren?

Ms. Lofgren. Aye.

The CLERK. Ms. Lofgren, aye. Ms. Jackson Lee?

[No response.]

The CLERK. Ms. Waters?

Ms. Waters. Aye.

The CLERK. Ms. Waters, aye. Mr. Meehan?

Mr. MEEHAN. Aye.

The CLERK. Mr. Meehan, aye. Mr. Delahunt?

Mr. Delahunt. Aye.

The CLERK. Mr. Delahunt, aye. Mr. Wexler?

Mr. WEXLER. Aye.

The CLERK. Mr. Wexler, aye. Ms. Baldwin?

Ms. Baldwin. Aye.

The CLERK. Ms. Baldwin, aye. Mr. Weiner?

[No response.]

The CLERK. Mr. Schiff?

Mr. Schiff. Aye.

The CLERK. Mr. Schiff, aye. Ms. Sánchez?

Ms. Sánchez. Aye.

The CLERK. Ms. Sánchez, aye. Mr. Chairman?

Chairman SENSENBRENNER. No. The CLERK. Mr. Chairman, no.

Chairman Sensenbrenner. Are there Members in the chamber who wish to cast or change their votes?

The gentleman from Wisconsin, Mr. Green?

Mr. GREEN. I have not reported.

The CLERK. Mr. Chairman, Mr. Green has not reported.

Mr. Green. I vote no.

The CLERK. Mr. Green, no. Chairman Sensenbrenner. The gentleman from Utah, Mr. Cannon?

Mr. Cannon. No.

The CLERK. Mr. Cannon, no.

Chairman Sensenbrenner. Are there further Members in the chamber who wish to cast or change their vote? If not, the clerk will report.

The gentleman from Michigan, Mr. Conyers?

Mr. Conyers. Yes.

The CLERK. Mr. Conyers, aye.

Chairman Sensenbrenner. Further Members who wish to cast or change their vote? If not, the clerk will try again.

The CLERK. Mr. Chairman, there are 12 ayes and 19 nays. Chairman SENSENBRENNER. The amendment is not agreed to.

The question is now on agreeing to the amendment relative to therapeutic cloning offered by the gentlewoman from California, Ms. Lofgren, upon which the noes prevailed by a voice vote.

Those in favor of the Lofgren amendment will, as your names are called, answer aye; those opposed, no, and the clerk will call the roll.

The CLERK. Mr. Hyde?

[No response.]

The CLERK. Mr. Coble?

Mr. Coble. No.

The CLERK. Mr. Coble, no. Mr. Smith?

Mr. Smith. No.

The CLERK. Mr. Smith, no. Mr. Gallegly?

Mr. Gallegly. No.

The CLERK. Mr. Gallegly, no. Mr. Goodlatte?

[No response.]

The CLERK. Mr. Chabot?

[No response.]

The CLERK. Mr. Jenkins?

Mr. Jenkins. No.

The CLERK. Mr. Jenkins, no. Mr. Cannon?

Mr. Cannon. No.

The CLERK. Mr. Cannon, no. Mr. Bachus?

Mr. Bachus. No.

The CLERK. Mr. Bachus, no. Mr. Hostettler?

Mr. Hostettler. No.

The CLERK. Mr. Hostettler, no. Mr. Green?

Mr. Green. No.

The CLERK. Mr. Green, no. Mr. Keller?

Mr. Keller. No.

The CLERK. Mr. Keller, no. Ms. Hart?

[No response.]

The CLERK. Mr. Flake?

Mr. Flake. No.

The CLERK. Mr. Flake, no. Mr. Pence?

Mr. Pence. No.

The CLERK. Mr. Pence, no. Mr. Forbes?

Mr. Forbes. No.

The CLERK. Mr. Forbes, no. Mr. King?

Mr. KING. No.

The CLERK. Mr. King, no. Mr. Carter?

Mr. CARTER. No.
The CLERK. Mr. Carter, no. Mr. Feeney?

Mr. Feeney, Mr. Feeney, no. Mrs. Blackburn?

Mrs. Blackburn. No.

The CLERK. Mrs. Blackburn, no. Mr. Conyers?

Mr. Conyers. Aye.

The CLERK. Mr. Conyers, aye. Mr. Berman?

[No response.]

The CLERK. Mr. Boucher?

[No response.]

The CLERK. Mr. Nadler?

Mr. Nadler. Aye.

The CLERK. Mr. Nadler, aye. Mr. Scott?

Mr. Scott. Aye.

The CLERK. Mr. Scott, aye. Mr. Watt?

Mr. Watt. Aye.

The CLERK. Mr. Watt, aye. Ms. Lofgren?

Ms. Lofgren. Aye.

The CLERK. Ms. Lofgren, aye. Ms. Jackson Lee?

[No response.]

The CLERK. Ms. Waters?

Ms. Waters. Aye.

The CLERK. Ms. Waters, aye. Mr. Meehan?

Mr. Meehan. Aye.

The CLERK. Mr. Meehan, aye. Mr. Delahunt?

Mr. Delahunt. Aye.

The CLERK. Mr. Delahunt, aye. Mr. Wexler?

Mr. WEXLER. Aye.

The CLERK. Mr. Wexler, aye. Ms. Baldwin?

Ms. Baldwin. Aye.

The CLERK. Ms. Baldwin, aye. Mr. Weiner?

[No response.]

The CLERK. Mr. Schiff?

Mr. Schiff. Aye. The Clerk. Mr. Schiff, aye. Ms. Sánchez?

Ms. Sánchez. Aye.

The CLERK. Ms. Sánchez, aye. Mr. Chairman?

Chairman SENSENBRENNER. No.

The CLERK. Mr. Chairman, no.

Chairman SENSENBRENNER. Are there Members in the chamber who wish to cast or change their vote?

The gentleman from Ohio, Mr. Chabot?

Mr. Chabot. No.

The CLERK. Mr. Chabot, no.

Chairman SENSENBRENNER. The gentlewoman from Pennsylvania, Ms. Hart?

Ms. HART. No.

The CLERK. Ms. Hart, no.

Chairman SENSENBRENNER. If there are no further Members who wish to cast or change their vote, the clerk will report.

The CLERK. Mr. Chairman, there are 12 ayes and 19 nays.

Chairman Sensenbrenner. And the amendment is not agreed to.

The question now is on reporting the bill favorably. A reporting quorum is present.

Those in favor of reporting the bill favorably will say aye.

Opposed, no.

The ayes have it.

A recorded vote is requested. Those in favor of reporting the bill favorably will, as your names are called, answer aye; those opposed, no, and the clerk will call the roll.

The CLERK. Mr. Hyde?

[No response.]

The CLERK. Mr. Coble?

Mr. Coble. Aye.

The CLERK. Mr. Coble, aye. Mr. Smith?

Mr. Smith. Aye.

The CLERK. Mr. Smith, aye. Mr. Gallegly?

Mr. Gallegly. Aye.

The CLERK. Mr. Gallegly, aye. Mr. Goodlatte?

[No response.]

The CLERK. Mr. Chabot?

Mr. Chabot. Aye.

The CLERK. Mr. Chabot, aye. Mr. Jenkins?

Mr. Jenkins. Aye.

The CLERK. Mr. Jenkins, aye. Mr. Cannon?

Mr. Cannon. Aye.

The CLERK. Mr. Cannon, aye. Mr. Bachus?

Mr. Bachus. Aye.

The CLERK. Mr. Bachus, aye. Mr. Hostettler?

Mr. Hostettler. Aye.

The CLERK. Mr. Hostettler, aye. Mr. Green?

Mr. Green. Aye.

The CLERK. Mr. Green, aye. Mr. Keller?

Mr. Keller. Aye.

The CLERK. Mr. Keller, aye. Ms. Hart?

Ms. HART. Aye.

The CLERK. Ms. Hart, aye. Mr. Flake?

Mr. Flake. Aye.

The CLERK. Mr. Flake, aye. Mr. Pence?

Mr. Pence. Aye.

The CLERK. Mr. Pence, aye. Mr. Forbes?

Mr. Forbes. Aye.

The CLERK. Mr. Forbes, aye. Mr. King?

Mr. King. Aye.

The CLERK. Mr. King, aye. Mr. Carter?

Mr. Carter. Aye.

The CLERK. Mr. Carter, aye. Mr. Feeney?

Mr. FEENEY. Mr. Feeney, aye. Mrs. Blackburn?

Mrs. Blackburn. Aye.

The CLERK. Mrs. Blackburn, aye. Mr. Conyers?

Mr. Conyers. No.

The CLERK. Mr. Conyers, no. Mr. Berman?

[No response.]

The CLERK. Mr. Boucher?

[No response.]

The CLERK. Mr. Nadler?

Mr. Nadler. No.

The CLERK. Mr. Nadler, no. Mr. Scott?

Mr. Scott. No.

The CLERK. Mr. Scott, no. Mr. Watt?

Mr. Watt. No.

The CLERK. Mr. Watt, no. Ms. Lofgren?

Ms. Lofgren. No.

The CLERK. Ms. Lofgren, no. Ms. Jackson Lee?

[No response.]

The CLERK. Ms. Waters?

Ms. Waters. No.

The CLERK. Ms. Waters, no. Mr. Meehan?

Mr. MEEHAN. No.

The CLERK. Mr. Meehan, no. Mr. Delahunt?

Mr. Delahunt. No.

The CLERK. Mr. Delahunt, no. Mr. Wexler?

Mr. Wexler. No.

The CLERK. Mr. Wexler, no. Ms. Baldwin?

Ms. Baldwin. No.

The CLERK. Ms. Baldwin, no. Mr. Weiner?

[No response.]

The CLERK. Mr. Schiff?

Mr. Schiff. No.

The CLERK. Mr. Schiff, no. Ms. Sánchez?

Ms. Sánchez. No.

The CLERK. Ms. Sánchez, no. Mr. Chairman?

Chairman SENSENBRENNER. Aye.

The CLERK. Mr. Chairman, aye. Chairman SENSENBRENNER. Are there additional Members in the chamber who wish to cast or change their votes?

[No response.]

Chairman Sensenbrenner. If not, the clerk will report.

The CLERK. Mr. Chairman, there are 19 ayes and 12 nays.

Chairman Sensenbrenner. And the motion to report favorably is agreed to.

Without objection, the Chairman is authorized to move to go to conference pursuant to House rules. Without objection, the staff is directed to make any technical and conforming changes, and all Members will be given 2 days, as provided by the House rules, in

which to submit additional dissenting, supplemental or minority views.

The chair thanks the Members for their cooperation. We don't have to come back this afternoon. Have a good lunch, and the Committee is adjourned.

[Whereupon, at 12:20 p.m., the Committee was adjourned.]

#### DISSENTING VIEWS

We strongly dissent from H.R. 534 as reported by the Judiciary Committee. We agree that human cloning—the production of children genetically identical to existing or previously existing human beings—is unsafe and unethical and should be prohibited. However, H.R. 534 would extend the bill's prohibitions far beyond the goal of banning human cloning and would prevent our citizens from

benefitting from ongoing or prospective stem cell research.

We must also object to the Committee considering this legislation without the benefit of a hearing this Congress. This is inappropriate for any piece of major legislation, but is particularly objectionable in the case of a life and death issue concerning complex and rapidly evolving technology. We also have five new members on our Committee and they are entitled to learn about this issue first hand. By not conducting a hearing, the Majority has done a disservice to the Committee, the Congress and the American peo-

ple.

The bill before us is so sweeping that it would not only ban reproductive cloning, but all uses of nuclear transfer—also known as therapeutic cloning—for research or medical treatment. This would block treatments designed to help persons suffering from Alzheimer's, diabetes, stroke, Parkinson's disease, heart disease, or spinal cord injury, to name but a few. If this bill passes into law, it would interfere with both privately and publicly funded stem cell research and would go so far as to ban a technique that could allow patients receiving stem cell treatments to avoid taking dangerous immunosuppressive drugs. The bill is so broadly written that it bans the importation of lifesaving medicines from other countries if their production is in any way derived from nuclear transfer. This means that if another nation's scientists used stem cell research to develop a cure for cancer, it would be illegal for persons living in this country to benefit from the drug. In addition, the legislation could operate to ban legal and unobjectionable infertility treatments. We further object that this bill would enforce genetic discrimination in stem cell research by limiting any future research to existing lines that in no way represent the genetic diversity of the human population.

It is for these reasons that numerous national organizations that represent patients and research institutions oppose this legislation and support H.R. 801 which would ban human cloning without endangering therapeutic cloning and stem cell research. These organizations include the Coalition for the Advancement of Medical Research, University of Wisconsin at Madison, Columbia University Health Sciences Division, American Society for Reproductive Medicine, Cancer Research and Prevention Foundation, Rett Syndrome Research Foundation, National Venture Capital Association, American Society of Hematology, Association of Reproductive Health

Professionals, Association of American Medical Colleges, Christopher Reeve Paralysis Foundation, American College of Obstetricians and Gynecologists, Hadassah, Resolve, Elizabeth Glaser Pediatric AIDS Foundation, Association of American Universities, Alliance for Aging Research, Children's Neurobiological Solutions Foundation, Project A.L.S.<sup>1</sup>

### Summary of Legislation and Democratic Concerns

H.R. 534 makes human somatic cell nuclear transfer into an egg a Federal felony. This nuclear transfer process consists of removing or inactivating the nuclear material of an egg and transferring into the egg the nuclear material and DNA from one or more human somatic cells (cells with the full complement of genes). There is no requirement that the transfer produce a child. The bill therefore criminalizes a scientific research process that takes place in a petri dish, regardless of the intent of the researcher or of the inability for this process to result in the birth of a cloned child.<sup>2</sup> The penalty for violating these provisions includes sanctions of a criminal fine and/or imprisonment for up to 10 years, and a civil penalty of at least \$1 million.<sup>3</sup>

Additionally, the bill makes it unlawful knowingly to attempt to perform nuclear transfer, to participate in such an attempt, or to ship, receive, or import for any purpose the embryos produced by nuclear transfer or products derived from such embryos. The importation of such products is prohibited regardless of whether they are capable of developing into a full human being; an American with an otherwise incurable disease therefore would be prohibited from importing a stem cell treatment developed abroad, where nuclear transfer research might be protected, if the stem cells were in any way derived from therapeutically cloned embryos.

By imposing these prohibitions, the bill would extend the reach of the criminal law into areas of pure scientific research. Currently, the Federal Government attempts to shape scientific research mainly through conditions on Federal funding. Making a Federal felony of somatic cell nuclear transfer (which takes place entirely in a petri dish, with no human or animal subjects) would represent an unprecedented intrusion of the criminal law into the scientific

process.

If H.R. 534 were to pass into law in its present form it would be difficult, if not impossible, for our nation to benefit from stem cell research that is currently ongoing or that would take place in the future. This is because somatic cell nuclear transfer holds the promise of leading to further breakthroughs in stem cell research that would bring the fruits of this research to the bedside to help patients. The bill prohibits the importation of safe and effective medical treatments, and it would use the criminal law to interfere with the scientific process and with advanced infertility treat-

<sup>3</sup>In cases involving a pecuniary gain, the civil penalty is to be no less than \$1 million and no more than twice the gross gain, if that sum exceeds \$1 million.

 $<sup>^1</sup>$ Letters From 27 Organizations to Representative Jim Greenwood (February, 2003). On file with the House Judiciary Committee.

<sup>&</sup>lt;sup>2</sup>The bill contains a "scientific research" exception for the use of cloning techniques to produce copies of DNA, tissues, organs, plants, or animals other than humans, but the research uses of nuclear transfer remain forbidden. Even if the oocyte had been modified so that it could not develop into a full human being, it would still be illegal to perform the transfer.

ments. For these and the reasons set forth herein, we dissent from the legislation.

### I. DEMOCRATS WOULD SUPPORT A BAN ON HUMAN CLONING, BUT H.R. $534~{ m GOES}$ TOO FAR

This Congress can and should outlaw the practice of human cloning. Experiments in animal cloning have revealed exceptionally high rates of deformities and birth defects, and the use of this procedure in humans has been almost unanimously rejected by the scientific community as unsafe to both mother and child.<sup>4</sup> Beyond issues of safety, using human cloning to produce a child would raise significant ethical problems, bringing the status of the child into question and raising severe dangers of abuse.<sup>5</sup> No pressing need exists to allow such cloning, and we believe it is appropriate for Congress to make the practice illegal. This is why at markup, Democrats voted in favor of the amendment offered by Rep. Lofgren which would have exempted research in therapeutic cloning from the ban and focused the bill on reproductive cloning. Unfortunately, the Lofgren amendment was defeated on a partyline vote.

By contrast, we cannot support the overbroad approach taken by H.R. 534. A ban on human cloning does not need to include a ban on nuclear transfer research. The former brings a new child into the world; the latter is concerned only with the study of embryonic development and the curing of disease. The Majority has argued that such research lies on a "slippery slope" that leads to reproductive cloning and beyond; but there is no sense in which reproductive cloning is the logical "next step" after nuclear transfer research. Nothing links the pursuit of stem-cell research to the deliberate creation of human beings. Even if such a link existed, Congress would still be perfectly capable of saying "this far, and no further."

The technique of *in vitro* fertilization has not brought the elimination of parenthood and the armies of test-tube babies that were originally feared; instead, it has allowed for millions of Americans to do what they were once told was impossible—to have a child of their own. In the same way, Congress can permit nuclear transfer research without accepting as necessary consequences the worst fears of its critics.

The Majority has also argued that a ban on reproductive cloning alone would be unenforceable. However, it has not for a moment explained how the government could enforce the prohibitions in

<sup>&</sup>lt;sup>4</sup>See generally Issues Raised by Human Cloning Research: Oversight Hearing Before the Subcomm. on Oversight and Investigations, House Comm. on Energy and Commerce, 107th Cong. (2001) (statements of Mark E. Westhusin, Associate Professor, Texas A&M University, and Rudolf Jaenisch, Professor of Biology, Massachusetts Institute of Technology); Rudolf Jaenisch and Ian Wilmut, Don't Clone Humans!, 291 SCIENCE at 2552 (March 30, 2001); FASEB Letter, at 1. To date, the only intentions to clone human beings have been expressed by a small number of groups and individuals far from the mainstream of the scientific community. Issues Raised by Human Cloning Research: Oversight Hearing Before the Subcomm. on Oversight and Investigations, House Comm. on Energy and Commerce, 107th Cong. (2001) (statement of Rael, leader of the Raelian movement).

<sup>&</sup>lt;sup>5</sup>A child who has the exact genetic makeup of another would have an unclear status under family law, and the attempt to duplicate an existing person would severely compromise the individuality of the cloned child. Additionally, human cloning might be misused by parents, who might place expectations on a cloned child's future (e.g., if the child is the clone of a basketball

H.R. 534. Anyone who is willing to break the law to clone a child will surely be willing to break the law to create an embryo. If a ban on the surgical procedure of implanting embryos into the uterus is unenforceable, a ban on a procedure that takes place in a petri dish in the privacy of a scientific laboratory is even more so. As Dr. Panos Michael Zavos testified before the committee in the 107th Congress, the technology to conduct nuclear transfer exists "in every IVF high-tech laboratory across the world," 55 of which are located in New York City alone.

Without putting police in the laboratory, there is no way for the government to prevent in advance an individual bent on violating the law; it can only rely on the deterrent effect of criminal penalties should the violation become known. The steps of implantation and gestation and the birth of a cloned child would clearly alert law enforcement to the violation, and a prohibition narrowly focused on reproductive cloning would provide the needed deterrent. Moreover, because H.R. 534 lacks any prohibition on the implantation of a cloned embryo into a woman's uterus, under its terms law enforcement would be helpless to prevent human cloning after the embryo stage. As a result, a narrowly focused ban would be just as effective in preventing human cloning, but would not have the unfortunate consequence of criminalizing lifesaving research.

### II. H.R. 534 WOULD PREVENT LIFESAVING RESEARCH IN THE UNITED STATES

The understanding of the workings of stem cells—the flexible cells that regenerate the body's tissue <sup>7</sup>—has advanced dramatically since 1998, when J.A. Thompson and other scientists first isolated stem cells from human embryos.<sup>8</sup> These undifferentiated cells <sup>9</sup> are the body's jacks-of-all-trades; they have the unique ability to become any kind of tissue found in the body—anything from blood or bone to nerves and heart muscles. As a result, embryonic stem cells offer immense potential to treat what have been thought to be incurable conditions by replacing the body's damaged tissue with healthy new cells.

In its report on the uses of stem cells, the National Institutes of Health described their medical potential as "enormous." <sup>10</sup> It concluded that transplants of stem cells could be used to treat condi-

<sup>&</sup>lt;sup>6</sup>Issues Raised by Human Cloning Research: Oversight Hearing Before the Subcomm. on Oversight and Investigations, House Comm. on Energy and Commerce, 107th Cong. (2001) (statement of Dr. Panos Michael Zavos).

7"A stem cell is a special kind of cell that here.

<sup>7&</sup>quot;A stem cell is a special kind of cell that has a unique capacity to renew itself and to give rise to specialized cell types. Although most cells of the body, such as heart cells or skin cells, are committed to conduct a specific function, a stem cell is uncommitted and remains uncommitted, until it receives a signal to develop into a specialized cell. Their proliferative capacity combined with the ability to become specialized makes stem cells unique." National Institutes of Health, Stem Cells: Scientific Progress and Future Research Directions (June 2001) [hereinafter "NIH Report"], at ES-1. Stem cells can be derived from any embryo, whether created from sexual (e.g., in vitro fertilization) or asexual (e.g., nuclear transfer) reproduction.

ual (e.g., in vitro fertilization) or asexual (e.g., nuclear transfer) reproduction.

\*S.J.A. Thompson et al., Embryonic stem cell lines derived from human blastocysts, 282 SCIENCE 1145–7 (1998).

<sup>&</sup>lt;sup>9</sup>Soon after the embryo is implanted in a woman's uterus, its cells begin to differentiate, changing their form to match the function they will perform in the fetus. Some will become muscle cells, others nerve cells, others skin cells. Embryonic stem cells are the original cells that have not yet differentiated and chosen their function; they therefore hold the potential to repair any of the body's organs.

<sup>10</sup>NIH Report, at 66.

tions as varied as Parkinson's disease, chronic heart disease, endstage kidney disease, and liver failure. 11 Rheumatoid arthritis, osteoporosis, and severe burns might all find new treatments. 12 Stem cells could repair damage to the nervous system from spinal cord injury, multiple sclerosis, and Alzheimer's. 13 Insulin-producing cells could be introduced to treat diabetes.14 Brain damage due to stroke could be reduced or reversed. 15 Replacement therapies could be created for autoimmune diseases such as lupus. 16 Survivors of heart attacks could be given healthy cardiovascular cells to heal damaged heart tissue and restore them to health.<sup>17</sup> Cancer patients who undergo severe chemotherapy could receive stem cell transplants to restore their blood cells and immune systems—and specialized new treatments could be developed to target and destroy individual cancer cells. 18 New treatments could even be discovered to restore function to paralyzed limbs, or to treat the degeneration caused by ALS (also known as Lou Gehrig's disease). 19 Finally, some have held out the hope of generating entire transplantable organs (bones, kidneys, and even hearts) through stem cell research.<sup>20</sup>

Nuclear transfer research of the type banned by H.R. 534 would be at the foundation of any medical treatment that took advantage of these discoveries. Like all transplants, stem cell treatments run the risk of being rejected by the patient's immune system. In fact, because stem cell transplants are so limited, they would be easy for the immune system to overwhelm. In its report, the NIH noted that there is a "very high" potential for immune rejection of these transplants; "Modifications to the cells, to the immune system, or both will be a major requirement for their use." 21 However, the NIH also found that if the stem cells were obtained from embryos produced by somatic cell nuclear transfer, they would bear the patient's DNA and would appear to the patient's body like his or her own cells, removing the risk of immune rejection. The transplant

<sup>&</sup>lt;sup>11</sup>NIH Report, at ES-4. <sup>12</sup>NIH Report, at 65; Robert P. Lanza *et al.*, *The Ethical Validity of Using Nuclear Transfer in Human Transplantiation*, 284 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 3715 (Dec. 27, 2000) [hereinafter "Lanza et al."].

<sup>&</sup>lt;sup>14</sup>Stem cells could be used to treat diabetes by replacing the damaged insulin-producing cells of the pancreas. The discovery of a stem-cell treatment for diabetes, for which there is currently no cure, would be a significant advance:

Each year, diabetes affects more people and causes more deaths than breast cancer and Each year, diabetes affects more people and causes more deaths than breast cancer and AIDS combined. Diabetes is the seventh leading cause of death in the United States today, with nearly 200,000 deaths reported each year. The American Diabetes Association estimates that nearly 16 million people, or 5.9 percent of the United States population, currently have diabetes. (NIH Report, at 67.)

15 NIH Report, at 77. The Report states that "Just a decade ago, neuroscience textbooks held that neurons in the adult human brain and spinal cord could not regenerate. Once dead, it was thought, central nervous system neurons were gone for good." New research and the possibilities of stem cell treatments promise to reverse that long-held medical dogma. Id.

16 NIH Report, at 62. The Report notes that lupus, a disease in which the immune system attacks the body's own cells, affects more than 239,000 Americans, over 90 percent of whom are women. African-American and Hispanic women are disproportionately affected. Currently, no treatment exists for the disease. Id.

treatment exists for the disease. Id.

<sup>&</sup>lt;sup>17</sup>NIH Report, at 87. Today, more than 4.8 million Americans suffer from congestive heart failure, with 400,000 new cases each year. Nearly 1.1 million Americans a year suffer from heart attacks. Stem cell treatments to repair the heart and circulatory system could therefore target "a major cause of death and disability in the United States." *Id.* <sup>18</sup>NIH Report, at ES-5.

<sup>&</sup>lt;sup>19</sup>NIH Report, at 79.

<sup>&</sup>lt;sup>20</sup> Lanza *et al.*, at 3715. <sup>21</sup> NIH Report, at ES-5.

could then take place without the use of dangerous immunosuppressive drugs—"a labor intensive, but truly customized therapy." <sup>22</sup> Nuclear transfer techniques are vital to realizing the potential of stem cell treatments and moving the science from the petri dish to the doctor's office.

H.R. 534 goes beyond banning reproductive cloning to ban research in somatic cell nuclear transfer. The result is that the bill would cut off scientific developments that are granting new hope to millions of Americans who have been told there is no cure. Forty Nobel Laureates, millions of patients, and even former First Lady Nancy Reagan, have recognized the therapeutic potential of these stem cell treatments derived from nuclear transfer techniques. In fact, the former First Lady recently used the occasion of husband's 92nd birthday to express her support for new legislation to allow the use of therapeutic cloning while banning reproductive cloning.<sup>23</sup>

By banning nuclear transfer techniques, H.R. 534 would additionally cut off research in new areas of regenerative medicine. As a leading researcher testified before the Subcommittee on Crime in the 107th Congress, it may soon be possible to turn a differentiated cell (such as a skin cell) back into an undifferentiated state, essentially creating compatible stem cells from the patient's own body. This procedure would avoid any need to use nuclear transfer and would not involve embryos in any way, offering the possibility of new medical treatments that would avoid the controversies that have accompanied stem-cell research. However, he testified that some nuclear transfer research will be "essential" for the early stages of understanding how stem cells gain their flexibility, and would be "a critical step to improve the usefulness of adult stem cells" as well.24 Nuclear transfer research would also provide a greater understanding of embryonic development that could be used to determine the causes of (and perhaps to prevent) birth defects, miscarriages, and juvenile diabetes. 25 The Federation of American Societies for Experimental Biology has echoed the NIH's language in describing such research: "The potential for treating human disease in this exciting area of regenerative medicine is enormous." 26 However, all of these promising advances would be blocked by H.R. 534.

Somatic cell nuclear transfer could also help our scientists better understand genetic causes of disease. We know that certain diseases, such as breast cancer, have a genetic component. By using SCNT, scientists could create cells that actually contain these genetic diseases and study their development. By comparing this to development of healthy cells, scientists could learn more about the progression of diseases which could lead to new cures and treatments. This too would be stopped by enactment of H.R. 534.

The Majority has sought to establish that the use of embryonic or cloned stem cells would be unethical when an alternative, name-

<sup>22</sup>NIH Report, at 17.

<sup>26</sup> FASEB Letter, at 2.

 $<sup>^{\</sup>sim}$  NIH Report, at 17.  $^{23}$  Letter from Nancy Reagan to Senator Orrin Hatch, January 29, 2003.  $^{24}$  Human Cloning: Hearings on H.R. 1644 and H.R. 2172 Before the House Subcomm. on Crime, 107th Cong. (2001) (Statement of Thomas Okarma, CEO of Geron, Inc.).  $^{25}$  Id.

ly adult stem cells, is available.<sup>27</sup> However, the studies necessary for regenerative medicine could not be accomplished with adult stem cells. Additionally, after surveying the current state of the science, the NIH concluded that embryonic stem cells have important advantages over adult stem cells: the latter cannot develop into as many different cell types; they cannot be generated in the same quantities in the laboratory; and they are difficult and sometimes dangerous to extract from an adult patient (especially stem cells located in the brain).<sup>28</sup> Given the very real benefits that this research could hold for those suffering Americans who are already living, it is appropriate for Congress at the very least to permit

such research to go on in the private sector.<sup>29</sup>

Unfortunately, H.R. 534 would prohibit this valuable research and leave no viable alternative, and it would do so permanently. At the markup, the Majority claimed that as the science progresses, researchers might convince a future Congress to repeal the research prohibition. But Congress should never establish a permanent criminal prohibition with an eye towards repealing it a few years later. Biomedical research progresses at an amazing speed; indeed, human pluripotent stem cells were first isolated in November 1998. Further advances are occurring at a dizzying pace, and a complete medical revolution may well occur within the next 5 years. It is for this reason that Rep. Linda Sánchez offered an amendment that would have made this bill sunset after 3 years, but it was defeated in a party line vote.

The maximum penalty for conducting nuclear transfer research under H.R. 534 is 10 years imprisonment. Legalizing nuclear transfer research after its potential has been realized would bring about the absurd result that the prison sentences would outlast the prohibitions—that scientists who practice nuclear transfer after its le-

<sup>27</sup> The Ethics of Human Cloning: Hearing Before the House Subcomm. on Crime, 107th Cong. (2001) (Statement of David Prentice, Professor of Life Sciences, Indiana State University). Cells with similar properties known as "embryonic germ cells" can also be obtained from aborted fetuses, but these will not necessarily be compatible with the patient's immune system. Furthermore, their source of origin makes them no less controversial to the Majority.

<sup>28</sup> NIH Report, at ES-9-10. It is important to note that at the stage when embryonic stemcell research normally occurs, the embryos are less than 14 days old and consist of a tiny ball of maliforantiated cells without original structure let alone a pervous system nerve

human subjects has occurred, nor has anyone suggested that it should. Lanza *et al.*<sup>29</sup> As Ronald M. Green, director of the Ethics Institute at Dartmouth College and former president of the Society of Christian Ethics, wrote to the Committee, H.R. 2505—the bill considered in the 107th Congress—should be rejected because it would go beyond a ban on human cloning to "prohibit several other very research directions of possibly great medical benefit." See Letter from Ronald M. Green to Chairman Sensenbrenner and Ranking Member Conyers (July 23, 2001) (on file with the minority staff of the House Judiciary Committee) [hereinafter "Green Letter"]

<sup>&</sup>lt;sup>28</sup>NIH Report, at ES-9-10. It is important to note that at the stage when embryonic stemcell research normally occurs, the embryos are less than 14 days old and consist of a tiny ball of undifferentiated cells, without organs or internal structure, let alone a nervous system, nerve impulses, feelings, or the capacity to feel pain. Even in the womb, the great majority of early embryos—as many as 80 percent—never develop into a human being. Furthermore, the separation of an embryo into twins or triplets frequently does not occur until after this stage of development, implying that the embryos cannot meaningfully be ascribed personal identity, uniqueness, or individuality. Lanza et al. As a number of prominent scientists and bioethicists have agreed, "The line established by gastrulation and the appearance of the primitive streak is a clear one, as is the line between therapeutic and reproductive cloning." Id. Even anti-choice Sen. Orrin Hatch has indicated that one should not equate a fetus in the womb, "with moving toes and fingers and a beating heart, with an embryo in a freezer." Sheryl Gay Stolberg, Morality and Medicine: Reconsidering Embryo Research, N.Y. TIMES (July 1, 2001), sec. 4, at 1. Great Britain has permitted research involving embryos since 1990, and no abuse of research involving human subjects has occurred, nor has anyone suggested that it should. Lanza et al.

ter"].  $^{30}\,\mathrm{This}$  argument was made by Rep. Coble when the Majority rejected Rep. Sánchez' amendment to provide for a 3-year sunset as recommend by the National Bioethics Advisory Commission. The argument was also made by the Majority's witness at our hearings in the 107th Congress. Human Cloning: Hearings on H.R. 1644 and H.R. 2172 Before the House Subcomm. on Crime, 107th Cong. (2001) (Statement of Alexander M. Capron, member of the National Bioethics Advisory Commission).

galization would be hailed as miracle workers and perhaps even afforded Federal funding, while their colleagues who first pioneered the techniques would still be in jail.

It is unclear how the effectiveness of nuclear transfer could be demonstrated to the Majority's satisfaction. We already have significant evidence regarding the potential of embryonic or cloned stem cells from animal research. While research involving human embryonic stem cells might continue, there will be no evidence regarding the effectiveness or suitability for testing of human stem cells obtained through nuclear transfer. We will never know what results might have been obtained had nuclear transfer research been legal, and if a permanent ban is placed on the research, we will never know enough to justify its decriminalization in the Majority's eyes.

### III. H.R. 534 WOULD PREVENT U.S. CITIZENS FROM BENEFITTING FROM LIFESAVING RESEARCH PERFORMED ABROAD

We also cannot support H.R.534 because the shipping, receipt and importation provisions are overbroad and would block Americans' access to lifesaving medical treatments produced abroad. The provisions in H.R. 534 would block not only the importation of cloned embryos, but also any product "derived" from such embryos, even if these products (such as stem cell-grown nerve tissue to restore paralyzed limbs) were unable to develop into a full human being. Moreover, since the critical term "derived" is not in any way elaborated on, under a plausible "fruits-of-the-tree" doctrine, the bill might even ban the importation of synthetic medicines modeled on proteins originally derived through this process in any way shape or form.

Representative Scott unsuccessfully offered an amendment to create an exemption for the shipping, receipt or importation of products to be used in medical treatment. Products that entered the country under this amendment would still have been required to undergo scrutiny by the Food and Drug Administration. Rejection of the Scott amendment clearly demonstrates that the legislation would keep safe and effective medical treatments out of the hands of U.S. citizens, even if the treatments have no chance what-

soever of being used for human cloning.

We fear that such a prohibition may have less to do with human cloning than with elevating the status of an embryo above that of live-born human beings.<sup>31</sup> There is no risk that an American hospital might try to clone a human using stem cells from abroad, and the Scott Amendment would have required that any imported material derived from a cloned embryo not be capable of producing a child. If researchers in Great Britain, where nuclear transfer research is legal and government-funded, were to discover a stem-

<sup>31</sup> The only argument offered by the Majority in defense of these provisions was that an exemption for medical treatment might provide a financial incentive to create more embryos through nuclear transfer. This argument is a red herring. If a British university discovers a cure for cancer or diabetes that relies on stem-cell research, it will have quite enough of a financial incentive already. Additionally, the absolute number of embryos should be irrelevant. If the Majority holds that legalizing nuclear transfer in the U.S. will make a ban on human cloning unenforceable, the same should hold true in Britain, and anyone who wishes to perform human cloning can simply travel there. Extra incentives to discover a cure for a terrible disease will not make the birth of a cloned child any more likely—they will only hasten the day when a

cell-based cure for cancer, the Majority would ban its importation simply because it was originally derived through nuclear transfer. In other words, the Majority is willing to sacrifice the lives and health of millions of suffering Americans in order to protect frozen embryos out of a vague fear that someone, somewhere, might perform human cloning. For a bill purported to protect our humanity, that rationale strikes us as somewhat ironic.

IV. H.R. 534 WOULD INTERFERE WITH STEM CELL RESEARCH—BOTH PRIVATELY FUNDED AND FUNDED BY THE NATIONAL INSTITUTES OF

The legislation's proponents would have us believe H.R. 534 has nothing to do with stem cell research and would not disrupt scientific advances being made in this important and much-discussed

area. Nothing could be further from the truth.

There are several reasons why the legislation would interfere with and undermine stem cell research. First is the fact that stem cells can be derived from embryos created by both sexual and asexual (e.g., nuclear transfer) means. As a basic and fundamental matter, by banning all forms of asexual reproduction based on cell nuclear transfer, the legislation would quite obviously limit stem cell research. It goes without saying that it will be more difficult to conduct stem cell research if one of the most promising techniques for

developing stem cells—therapeutic cloning—is criminalized.

Second, if research were performed based solely on stem cells derived from sexual means (such as additional embryos formed through in vitro fertilization), it will be difficult to derive any practical benefit from the research without the benefit of nuclear transfer. If a scientist were to use IVF-derived stem cells to design a treatment for Alzheimer's disease, it still could not easily be applied to any patients without the utilization of therapeutic cloning. This is because, as we have noted above, scientists can greatly reduce the risk of immune rejection if we use stem cells which bear a patient's own DNA derived from therapeutic cloning rather than adult stem cells. This means that the potential benefits of President Bush's August, 2001 order permitting the use of existing stem cell lines for research purposes would also be snuffed out by this law by limiting the ability to translate research into real disease therapies.

This conclusion is supported by the NIH in their July 18, 2001, study finding that embryonic stem cells have important advantages over adult stem cells. The NIH recognized that adult stem cells cannot develop into as many different cell types; they cannot be generated in the same quantities in the laboratory; and they are difficult and sometimes dangerous to extract. It is also critical to note that the NIH has specifically stated that somatic cell nuclear transfer would be a "truly customized" way of creating stem cell transplants that would not be rejected by the body's immune sys-

Third, although the NIH does not presently conduct research using human somatic cells, that decision has been made voluntarily by scientists and the executive branch, not statutorily by Congress.

<sup>32</sup> NIH Report, at 17.

By passing a one-size fits all ban, we will permanently and inflexibly ban the practice, tying the hands of future scientists and the Administration alike. This is in direct contradiction of the NIH's own conclusion that it is premature to discard the potential benefits of new forms of stem cell research.<sup>33</sup>

Fourth, because the legislation prohibits the shipping, receipt, or importation of embryos produced abroad by nuclear transfer or of products derived from such embryos, NIH would not be able to benefit from many forms of research conducted abroad involving stem cells. This would put our own scientists at a distinct disadvantage compared to other nations' researchers in the race to develop cures for crippling and fatal diseases. At present there is no law which prevents the NIH from acquiring foreign products in any way derived from therapeutic cloning techniques. H.R. 534, however, provides an inflexible and permanent ban which restricts our own Administration.

Finally, if the Majority did not believe that the bill would undermine stem cell research, they would have had little reason to reject the Lofgren amendment exempting stem cell research from the bill's prohibitions. If we truly want to insure that stem cell research is not interrupted, we would carve the activity from out of the bill's reach. However, the Majority rejected this notion, in a straight party-line vote.

## V. H.R. 534 WOULD BAN LEGAL AND UNOBJECTIONABLE INFERTILITY TREATMENTS AND TECHNIQUES OF $IN\ VITRO$ FERTILIZATION

H.R. 534 further exceeds its mandate to prohibit human cloning by bringing the heavy penalties of the criminal law to bear on infertility treatments that have nothing to do with human cloning. Over the past 4 years, the process of "ooplasmic transfer" has been used in connection with *in vitro* fertilization to help more than 30 infertile couples conceive a healthy child.<sup>34</sup> The process involves the replacement of some of the cytoplasm (the fluid that constitutes the bulk of a cell) in an infertile woman's egg with cytoplasm from a healthy donor egg or other cell. The original egg has been fertilized with genetic material from the husband and will develop normally, thanks to the infusion of healthy cytoplasm.

However, the definition of "human cloning" in H.R. 534 is so overbroad as to likely ban this procedure. The bill includes under the definition the introduction of any "nuclear material" from "one or more human somatic cells" into an egg whose nuclear material has been removed or inactivated. Yet the technique described above (and possibly other techniques of *in vitro* fertilization as well) could introduce into the fertilized egg some of the donor cell's mitochondria, the "power plants" that float in the cytoplasm and generate energy for the cell. Mitochondria are unique because they have their own DNA and reproduce on their own. Thus, the introduction of mitochondria from a healthy, mature cell into a fertilized egg would yield a new organism that is genetically virtually identical to the pre-transfer egg, yet with slightly different mitochondrial DNA. It might therefore be considered to be "human cloning," even

<sup>33</sup> NIH Report, at ES-10.

<sup>34</sup> Infertility Treatment Leaves Kids With Extra DNA, REUTERS (May 7, 2001).

though the resulting child would have genes from both parents, and would bring 10-year jail sentences on the participants under H.R. 534.

At the very least, a ban on this technique of *in vitro* fertilization is a plausible reading of H.R. 534. Passage of H.R. 534 without including a protection for in vitro fertilization runs the risk that future courts will find accepted and beneficial fertility treatments in violation of the criminal law, and that infertile couples will be denied a safe and effective means of conceiving children.

#### VI. H.R. 534 WOULD FREEZE IN PLACE STEM CELL RESEARCH BUILT ON GENETIC DISCRIMINATION

Another problem with this legislation is that it freezes in place a regime of permitted stem cell research built on genetic discrimination. President Bush has issued an order limiting stem cell research to the seventy or so existing stem cell lines as of August 9, 2001.<sup>35</sup> H.R. 534 would take that directive and set it in stone with regard to embryonic stem cells. Of the estimated 70 stem cell lines grand-fathered by President Bush's order, only a handful are usable. 36 As a recent Institute of Medicine study explained in detail, the resulting problem is that the fewer cell lines available to re-

searchers, the lower the genetic diversity they represent.<sup>37</sup>

Federal health officials have reported that the stem cell lines in existence are from only 10 companies and research laboratories located in Singapore, Scandinavia, India, Australia and the United States.<sup>38</sup> These existing stem cell lines have been cultivated primarily from embryos left over from in-vitro clinics where the clientele, and thus the resulting embryos, tend not to represent the genetic, racial and ethnic diversity of the human population. Not surprisingly, there are few, if any, lines derived from African Americans. As Professor Irv Weissman of Stanford University has stated, "to really understand disease, we must also research diseased cells, which these lines do not represent. Nor do they represent diversity of our population. Genetic diseases discriminate. Disease that plague minority populations are almost certainly not represented in the 64 approved stem cell lines". <sup>39</sup> This means that it is next to impossible to research diseases which are more prevalent in people of particular racial or ethnic groups, such as sickle cell disease among African Americans or Tay Sachs among Jews. Weissman contends that the only way to create more diverse stem cell lines is through somatic cell nuclear transfer. However, this bill would make such a practice a crime, and would consequently create a biotech divide in which significant segments of our population would be excluded from the benefits of this innovative research.

Representatives Nadler and Jackson Lee offered an amendment that was rejected that would have amended H.R. 534 to permit ad-

<sup>35</sup> National Institute of Health, "Notice of Criteria For Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry", November 7, 2001, http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html

36 Ted Ages, Coming Clean on Stem Cells, The Scientist, January 21, 2003. http://www.camradvocacy.org/fastaction/news.asp?id=488

37 "Stem Cells and the Future of Regenerative Medicine (2002)", p.48. http://books.nap.edu/books/0309076307/html/1.html
38 Brian Vastag Suddenly 64 Stem Cell Lines 286 IAMA 1162 (2001)

ooks/03090/03090/Intml/1.1tml 38 Brian Vastag. Suddenly, 64 Stem Cell Lines, 286 JAMA 1163 (2001). 39 Irv Weissman, It Doesn't Have to Be This Way, 3 Cures Now 2 (February 2003).

ditional stem cell research solely for the purpose of creating genetically diverse cell lines. This amendment would have helped to ensure that the research that is being done is not done on a discriminatory basis. For this reason, the more than 300,000 members of Hadassah Women's Zionist Organization and the Steven and Michele Kirsch foundation have written in strong support of such an amendment.<sup>40</sup> However, the Majority has argued that this amendment would create a loophole in the bill that would permit the cloning of human beings. However, the amendment would have done nothing of the sort in creating an exemption that would allow only for the cloning of single cells for the purpose of generating genetically diverse embryonic stem cells.

#### Conclusion

Because it far exceeds its mission of prohibiting human cloning, H.R. 534 can be seen as an attempt to do secretly what the Administration would hesitate to do publicly: ban the use of stem-cell-based treatments in the United States. If H.R. 534 becomes law, it would be difficult, if not impossible, to derive any practical benefit from stem cell research, because we would be unable to implement its discoveries through nuclear transfer or therapeutic cloning.

Under H.R. 534, the new discoveries and medical cures resulting from stem cells will be off-limits to Americans who cannot afford to travel abroad to countries where nuclear transfer research is still pursued. The production of such treatments would be prohibited domestically, and the importation of even a cancer cure from abroad would carry a 10-year prison sentence. Furthermore, the vagueness and overbreadth of H.R. 534 run the risk of prohibiting legitimate and uncontroversial techniques of *in vitro* fertilization that could help thousands of couples conceive their own children. The legislation also freezes in place a stem cell research regime that genetically discriminates. H.R. 534 represents far more than a ban on human cloning: it represents an intrusion of the criminal law into scientific progress, and it should be rejected.

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RICK BOUCHER.
JERROLD NADLER.
ROBERT C. SCOTT.
MELVIN L. WATT.
ZOE LOFGREN.
SHEILA JACKSON LEE.
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ROBERT WEXLER.
TAMMY BALDWIN.
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<sup>&</sup>lt;sup>40</sup>Letter from Bonnie Lipton, National President of Hadassah to Congressman John Conyers, Jr. (February 21, 2003); and Letter from Susan E. Frank, Vice President of Public Policy of Kirsch Foundation to Congressman John Conyers, Jr (February 11, 2003).